



Office of the Deputy Attorney General
Washington, D.C. 20530

November 7, 2008

Fighting the fraud and theft committed by these criminals is vital to preserving our health care system – vital to its financial solvency, as well as its integrity. The Department's attorneys and agents make up our front line in stopping those criminals, and I want to thank you for all that you do.

Attorney General Michael Mukasey
May 28, 2008

Dear United States Attorneys:

America leads the world in quality health care. Each year our government spends billions of dollars to make that care available to individuals who might not otherwise be able to afford it, including veterans, children, the elderly and the poor. But with such expansive government spending for health care comes the potential for fraud and abuse. When I was an Assistant United States Attorney for the Northern District of Illinois, I saw, as you see, how health care fraud and abuse can badly hurt the intended beneficiaries of government health care programs and drain resources we need to help the truly deserving.

The efforts of the Department of Justice to fight this fraud and abuse, led by your hard work in this area, are necessary to maintain the quality and integrity of our nation's health care system. Ensuring that abuses in the provision of health care are appropriately addressed is an important priority of the Department of Justice and its components, including the Federal Bureau of Investigation. Working with your law enforcement partners throughout federal and state enforcement agencies, you work tirelessly to bring to justice those who would prey on the vulnerabilities of government programs intended to help our most vulnerable citizens. I speak on behalf of the Attorney General and the leadership offices within the Department when I express our sincere gratitude for your efforts.

Keep up the good work. I, and your country, thank you.

Sincerely,

A handwritten signature in black ink that reads "Mark Filip".

Mark Filip
Deputy Attorney General

Health Care Fraud

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**January
2009**

**Volume 57
Number 1**

United States
Department of Justice
Executive Office for
United States Attorneys
Washington, DC
20530

Kenneth E. Melson
Director

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The United States Attorneys'
Bulletin is published pursuant to
28 CFR § 0.22(b).

The United States Attorneys'
Bulletin is published bimonthly by
the Executive Office for United
States Attorneys, Office of Legal
Education, 1620 Pendleton Street,
Columbia, South Carolina 29201.

Managing Editor
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Internet Address
[www.usdoj.gov/usao/
reading_room/foiamanuals.
html](http://www.usdoj.gov/usao/reading_room/foiamanuals.html)

Send article submissions and
address changes to Program
Manager, United States Attorneys'
Bulletin,
National Advocacy Center,
Office of Legal Education,
1620 Pendleton Street,
Columbia, SC 29201.

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Pharmaceutical Marketing Fraud Under the False Claims Act

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I. Introduction

In recent years some of the United States' largest False Claims Act (FCA) recoveries have been from pharmaceutical companies. For example, in October 2005, Serono, S.A. agreed to pay \$704 million to resolve criminal charges and civil allegations in connection with the marketing and sales of its drug, Serostim. Press Release, U.S. Department of Justice, Serono to Pay \$704 Million for the Illegal Marketing of AIDS Drug (Oct. 17, 2005), *available at* http://www.usdoj.gov/opa/pr/2005/October/05_civ_545.html.

In May 2007 the Purdue Frederick Company agreed to pay \$634 million for misbranding its drug, OxyContin. Press Release, U.S. Attorney, Western District of Virginia, The Purdue Frederick Company, Inc. and Top Executives Plead Guilty to Misbranding Oxycontin; Will Pay Over \$600 Million (May 10, 2007), *available at* http://www.usdoj.gov/usao/vaw/press_release/purdue_frederick_10may2007.html.

In September 2007 Bristol-Myers Squibb Company and a subsidiary agreed to pay more than \$515 million to settle their civil liability for various drug marketing and pricing practices, including off-label promotion of the drug, Abilify. Press Release, U.S. Department of Justice, Bristol-Myers Squibb to Pay More than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (Sept. 28, 2007), *available at* http://www.usdoj.gov/opa/pr/2007/September/07_civ_782.html.

In February 2008 Merck & Company agreed to pay over \$650 million to resolve allegations that it failed to pay the proper rebates to Medicaid and paid kickbacks to induce physicians to use its

various products. Press Release, U.S. Department of Justice, Merck to Pay More than \$650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks (Feb. 7, 2008), *available at* http://www.usdoj.gov/opa/pr/2008/February/08_civ_094.html. And in September 2008 Cephalon agreed to pay \$425 million to resolve allegations that the company off-label marketed three of its drugs. Press Release, U.S. Department of Justice, Biopharmaceutical Company, Cephalon, to Pay \$425 Million & Enter Plea to Resolve Allegations of Off-Label Drug Marketing (Sept. 29, 2008), *available at* <http://www.usdoj.gov/opa/pr/2008/September/08-civ-860.html>.

With Medicare Part D now covering a wide array of prescription drugs, prosecutors can expect to see more and more of these cases.

Generally speaking, pharmaceutical companies can violate the FCA in two basic categories: marketing and pricing. This article discusses cases in the marketing category and offers some views on the factors that can make a compelling FCA case.

II. Legal background

Marketing fraud cases can involve kickbacks and/or off-label marketing, and the two often go hand in hand. A company off-label markets when it promotes a drug for an indication or dosage not approved by the Food and Drug Administration (FDA) as safe and effective. Promoting a drug in this way can render it adulterated and misbranded under the Food, Drug, and Cosmetics Act (FDCA), 21 U.S.C. §§ 301-3991(2000). Paying doctors in order to induce drug prescriptions may violate the Medicare Anti-Kickback Act (AKA), 42 U.S.C. § 1320a-7b (1990).

Either type of violation can result in the submission of false claims to federally-funded programs, thereby potentially violating the FCA.

The FCA imposes treble damages and civil penalties on, inter alia, any person who knowingly presents, or causes to be presented, to the Federal Government a false or fraudulent claim for payment or approval, or who knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim approved or paid by the Federal Government. 31 U.S.C. § 3729(a)(1), (2) (1994).

A. Falsity

Generally, the federal health care programs will pay for a drug only if it is prescribed for the FDA-approved indication (i.e., on label), but will pay for off-label uses if they are supported by one of the three pharmaceutical compendia listed at 42 U.S.C. § 1396r-8(g)(1)(b)(1) (1984) (i.e., DRUGDEX, American Hospital Formulary Service, or U.S. Pharmacopeia-Drug Information). See 42 U.S.C. 1396r-8(k)(6) (1984) (Medicaid); 42 C.F.R. § 423.100 (2005) (Medicare Part D). The rules for Medicare Part B are slightly different: Part B will cover an outpatient drug administered incident to a physician's services if it is used for the FDA-approved indication, or if the Medicare carrier determines that the use is medically accepted, taking into account the compendia, authoritative medical literature, and/or accepted standards of medical practice. See Medicare Benefit Policy Manual, Chap. 15, § 50.4.1 & .2, available at <http://www.cms.hhs.gov/Manuals/downloads/bp102c15.pdf>. When a federal health care program does not cover an off-label use of the drug, but a claim is submitted for that off-label use as if the claim is proper and should be paid, the claim will generally be false. This analysis is really no different from the analysis in the more familiar contract fraud context, for example. When a government contractor performs work that is not allowable under the contract, but submits an invoice to the government for that work as if it is allowable and should be paid, the claim is generally false.

Similarly, federal health care programs will not pay claims that were induced by kickbacks. The AKA prohibits knowing and willful payment of remuneration to induce another to refer or arrange for a health care item or service

reimbursable under a federal health care program. 42 U.S.C. § 1320a-7b(b) (1990). The courts have generally agreed with the United States' position that compliance with the AKA is a prerequisite to payment of federal health care funds, and therefore that claims induced by kickbacks can constitute false claims under the FCA. See, e.g., *United States ex rel. McNutt v. Haleyville Medical Supplies*, 423 F.3d 1256, 1260 (11th Cir. 2005); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244-45 (3d Cir. 2004); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902-03 (5th Cir. 1997); cf. *United States v. Rogan*, 517 F.3d 449, 451-53 (7th Cir. 2008) (case involved AKA and Stark Amendment to the Medicare Act, 42 U.S.C. § 1395nn, but opinion relied on "the fact that the Stark Amendment forbids federal reimbursement for services that stem from compensated referrals"). It should be noted, however, that in a criminal case, the Eleventh Circuit found that kickbacks alone did not establish criminal health care fraud under 18 U.S.C. § 1347; the court stated that a knowing false or fraudulent misrepresentation to Medicare would also be required for criminal liability. *United States v. Medina*, 485 F.3d 1291, 1298 (11th Cir. 2007).

B. Claims

Improper marketing by a pharmaceutical company does not automatically violate the FCA. As the First Circuit has explained, "FCA liability does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the FDCA, that are independent of any false claim." *United States ex rel. Rost v. Pfizer*, 507 F.3d 720, 727 (1st Cir. 2007) (*Rost I*). In pharmaceutical fraud cases, it is usually someone other than the drug company (such as a health care provider or beneficiary) who submits the claims to the government. Accordingly, to establish an FCA violation by the pharmaceutical company, the government should tie the company's conduct to claims that were submitted to federally funded programs. *Id.* at 732 (dismissing relator's complaint for lack of particularity under Federal Rule of Civil Procedure 9(b); allegations of drug company's illegal practices were not a sufficient basis for

FCA action because they did not involve claims for government reimbursement); *United States ex rel. Rost v. Pfizer*, 2008 WL 4293642 at *5 (D. Mass. Sept. 18, 2008) (*Rost II*) (on remand, permitting amended complaint which alleged specific false claims to go forward).

C. Defendant's state of mind

FCA liability attaches to "knowing" conduct, and the statute defines "knowingly" to mean that the defendant has actual knowledge of the falsity at issue, acts in deliberate ignorance of the truth or falsity, or acts in reckless disregard of the truth or falsity. 31 U.S.C. § 3729(b) (1994).

In addition, the Supreme Court recently held that a plaintiff pursuing an action under 31 U.S.C. § 3729(a)(2) (making or using a false record or statement to get a false or fraudulent claim paid) "must prove that the defendant intended that the false record or statement be material to the Government's decision to pay or approve the false claim." *Allison Engine Co. v. United States ex rel. Sanders*, 128 S. Ct. 2123, 2126 (2008). *Allison Engine* also imposes a similar requirement on actions brought under Section 3729(a)(3) (conspiracy to defraud the government by getting a false or fraudulent claim paid). *See id.* at 2130-31 (plaintiff must show that the conspirators "intended 'to defraud the Government,'" and in conspiracy cases involving false records or statements, plaintiff must show that the conspirators "agreed that the false record or statement would have a material effect on the Government's decision to pay the false or fraudulent claim").

Thus, an FCA case against a pharmaceutical company should include evidence that the company was at least reckless or deliberately ignorant in engaging in the offending conduct, rather than, for example, negligently mistaken. In addition, in cases brought under 31 U.S.C. § 3729(a)(2) or (3), we should be prepared to show that the company was aware that false claims would be submitted to the United States based on the company's marketing conduct.

III. Some key factors in evaluating pharmaceutical fraud cases

A pharmaceutical marketing fraud case typically comes to us in the form of an FCA qui tam action brought by an employee or former employee (known as the relator) who has some knowledge of the company's marketing practices. *See* 31 U.S.C. § 3730(b). However, the relator often lacks a full picture of the company's conduct and may not know the relevant government agencies' view of that conduct, including whether the off-label use at issue is specifically covered by any of the federal health care programs. Moreover, the relator has a built-in bias, since he or she is generally entitled to a percentage of the United States' recovery. *See* 31 U.S.C. § 3730(d). Accordingly, as is the norm in qui tam cases, it is the government's responsibility to gather and assess the evidence and determine whether the defendant's conduct violates the FCA, and whether the FCA case is a strong one to pursue. While there is certainly no set formula for evaluating the strength of an FCA case, several key factors are offered for consideration below.

A. Government agencies' involvement

Allegations of off-label marketing for a use supported by the compendia, or specifically covered by a state Medicaid agency or Medicare carrier, may not make the most compelling FCA case. *Cf. Rost*, 2008 WL 4293642 at *6 ("if a state knowingly chose to reimburse for a drug, even for an off-label use, after a prior authorization review, liability would not attach"). On the other hand, if the drug company used false or misleading information to get the off-label use covered, that can be good evidence of knowledge and misconduct, making a potentially strong FCA case. Of course, even if an off-label use is supported by the compendia or specifically approved for payment, a compelling FCA case can be made if the claims to federal health care programs were caused by kickbacks. *See id.*

The company's interactions with the FDA can also be relevant. For example, drug companies are required to submit their promotional materials

to the FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) for review. 21 C.F.R. § 314.81(b)(3)(i) (2007). A recent report by the United States Government Accountability Office (GAO) calls this "[t]he primary mechanism FDA uses to oversee off-label promotions." U. S. GEN. ACCOUNTING OFFICE, PRESCRIPTION DRUGS: FDA'S OVERSIGHT OF THE PROMOTION OF DRUGS FOR OFF-LABEL USES, GAO-08-835, July 2008, at 13, *available at* <http://www.gao.gov/new.items/d08835.pdf>. Thus, if a company used a brochure to market a drug for an off-label use, but failed to submit the brochure to DDMAC, that failure might serve as evidence that the company knew it was improperly marketing the drug. However, the opposite is not necessarily true; DDMAC's mere failure to object to off-label information in materials submitted by the company does not constitute approval of the company's off-label marketing. As explained in the GAO report, DDMAC receives substantially more materials than it has capacity to review. *Id.* at 16 (annual number of items received has been increasing and reached over 68,000 in 2007). Therefore, the government is often unaware of a company's improper marketing practices until a qui tam suit is filed.

B. Defendant's conduct

Just as in any other FCA case, the more egregious the defendant's conduct, the more compelling the case is likely to be. In a drug marketing case, some of the more egregious conduct might include the company's sales representatives providing false information to doctors or paying a quid pro quo for the doctor's prescriptions. If the direction to engage in this conduct comes from high-level management, that makes the case all the more compelling.

It is also important to look for a nexus between the defendant's conduct and the submission of the false claims to the government program. As discussed above, typically the drug company does not submit claims to the government. In an FCA case against a pharmaceutical company, it is important to show that the company caused the false claim to be submitted to the government. *See United States ex*

rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001); *Rost I*, 507 F.3d at 732-33 & n.9. Of course, the closer and clearer the nexus between the company's conduct and the submission of the claim to the government, the more compelling the case will be. For example, in an off-label marketing case, it would appear impossible to find a nexus between the company's conduct and the false claim if the doctor prescribed a drug for an off-label use based on legitimate independent studies supporting the off-label use, without ever hearing about the use from the company's employees or company-paid speakers. On the other hand, it should be easy to show a nexus in a case where the doctor obtained all of the off-label information from the company's sales representative and the doctor's prescriptions increased after hearing the sales representative's off-label pitch. Naturally, the evidence in most cases will fall somewhere between these two extremes and it will sometimes be a judgment call whether the evidence is sufficient to tie the defendant's conduct to the submission of the false claims.

In cases under 31 U.S.C. § 3729(a)(2) or (3), it should be shown that the company was aware that claims would be submitted to the United States based on the company's marketing conduct. *See Allison Engine*, 128 S. Ct. at 2126. As the *Allison Engine* opinion is new, it is not entirely clear what type of evidence the courts will require in this regard. In the pharmaceutical fraud arena, possibilities might include:

- Evidence that the company was aware that a federal health care program paid for substantial amounts of the drug at issue;
- The company provided assistance to patients and doctors seeking reimbursement from federal health care programs; or
- The company attempted to get state Medicaid agencies, Medicare contractors, or similar entities to cover the off-label use of the drug.

C. Damages

It goes without saying that the amount of monetary harm to the government is an important factor in assessing any FCA case. In the off-label

arena, it should be remembered that the damages do not necessarily include all of the money that the government has paid for off-label sales. Again, it is important to show a nexus between the defendant's conduct and the submission of the claim. For example, the evidence may show that a certain amount of off-label prescriptions were written completely independent of the company's marketing practices. However, just because a company's off-label marketing practices stopped at a certain point does not mean the damages stopped at the same time. If supported by the evidence, it can be argued that continued claims to federal programs for off-label uses were the residual result of past marketing practices.

Additional concerns apply in Medicare Part A cases. Since Part A pays a set price for inpatient stays under the diagnosis-related grouping (DRG) system, it is unlikely that the typical off-label case will include damages to the Part A program. On the other hand, it is important to check for false claims to various programs, and not just Medicare and Medicaid. The Department of Veterans Affairs, TRICARE (military health plan), and the Federal Employee Health Benefits Program can have significant damages in pharmaceutical cases.

In kickback cases, calculating damages can present a challenge. It is certainly possible to argue that the government was damaged by the total amount of paid claims that were achieved by kickbacks, even if medically necessary services were rendered. The Seventh Circuit's opinion in *Rogan*, although predicated mainly on the Stark Amendment rather than the AKA, supports this damages methodology. *See Rogan*, 517 F.3d at 453 ("The government offers a subsidy (from the patients' perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that Edgewater received on these 1,812 claims must be paid back.") This methodology is consistent with longstanding FCA law in other types of health care fraud cases. *See, e.g., United States v. Mackby*, 339 F.3d 1013, 1017 (9th Cir. 2003); *Peterson v. Weinberger*, 508 F.2d 45, 49 (5th Cir. 1975); *see generally United States v. Woodbury*, 359 F.2d 370, 379 (9th Cir. 1966) ("Ordinarily the measure of the government's damages would be the amount

that it paid out by reason of the false statements over and above what it would have paid if the claims had been truthful.") However, in a criminal case, the Eleventh Circuit found that the amounts paid on claims arising from kickbacks were not a loss to the Medicare program. *Medina*, 485 F.3d at 1304 (11th Cir. 2007).

D. Safety

Finally, all of the other factors can be overshadowed by the potential for patient harm. For example, in an off-label case, safety concerns with the off-label use at issue can make a case extremely compelling. On the other end of the spectrum, if the drug has no safety issues and is actually effective for the off-label use, that does not provide a legal defense but it probably makes the case much less compelling. A similar analysis can be applied to kickback cases. For example, the pharmaceutical company may be paying doctors to write prescriptions at a dangerously high rate or in patient populations that implicate safety issues. While the absence of safety concerns does not negate the kickbacks, their presence would generally make the case more worthwhile to pursue. It goes without saying that when a case brings serious safety concerns to the government's attention, it is incumbent upon the government to address the safety issues in some way, whether via the FCA or otherwise. ❖

ABOUT THE AUTHOR

❑ **Sara Winslow** is a Deputy Chief of the Civil Division in the Northern District of California. She specializes in False Claims Act cases, including pharmaceutical and other health care fraud matters.✉

The Office of Consumer Litigation and Recent Pharmaceutical Company Settlements

Eugene Thirolf
Director
Office of Consumer Litigation

I. Introduction

Over the last 3 years, the pharmaceutical industry has paid more than \$2 billion to the United States to settle Food, Drug, and Cosmetic Act (FDCA) and False Claims Act (FCA) charges. The criminal fines and civil settlements resulting in these large sums of money have generated an important public health debate and raised significant interest in the media and Congress. The publicity can be highly favorable or significantly skeptical of the government's actions. Simply put, these Food and Drug Administration (FDA) cases involve a mix of scientific, medical, and public health issues. Unlike most fraud cases, the interplay of those considerations can create disagreement among concerned parties and draw the spotlight of the media and Congress. Likewise, because these crimes can directly affect the public health, the failure to aggressively investigate and prosecute may lead to unacceptable risks to the public.

The Office of Consumer Litigation (OCL) deals with FDA cases every day and its attorneys can help assess these types of cases and highlight many of the factors that may not be immediately apparent when a case is initially referred to a United States Attorney's office. This article responds to numerous requests by Assistant United States Attorneys (AUSAs) to publicize OCL and these pharmaceutical industry recoveries.

II. Background

OCL is in the Civil Division of the Department of Justice (Department). The attorneys in this section are directed to prosecute both criminal and civil cases. 28 C.F.R. § 0.45(j). The office is both a resource for AUSAs faced with cases arising under a variety of federal consumer protection statutes and a reviewer of proposed enforcement actions under those statutes. A substantial number of AUSAs have worked with OCL but many others are not aware of the section's services. This article shows how United States Attorneys' offices can achieve significant results working with OCL.

OCL has been the component of Main Justice with responsibility for civil and criminal litigation under the FDCA. OCL was established in 1971 and has performed its consumer protection functions since 1984 in the Civil Division. OCL works closely with the FDA, the Department of Health and Human Services Office of Inspector General, United States Attorneys' offices across the country, and the Civil Frauds Section of the Commercial Litigation Branch of the Civil Division.

The settlements discussed below involve so-called off-label marketing activities by drug companies. OCL typically becomes involved in these off-label marketing investigations either because a matter is referred to it by the FDA or a qui tam complaint includes an allegation that the FDCA was violated.

These large civil and criminal prosecutions involving violations of the FDCA are approved by the Assistant Attorney General of the Civil Division, who oversees both OCL and the Civil Frauds Section.

III. Off-label violations

What is an off-label marketing violation? In 2005 at the Second Annual Pharma, Biotech and Device Colloquium at Princeton University, then-Associate Attorney General, Robert McCallum, discussed what off-label drug promotions could be violations. The framework that the Associate Attorney General set forth in his speech continues to guide the Department's enforcement activities in this area.

FDA approves drugs for specific uses. A doctor in his or her own medical judgment may prescribe a drug for a use not approved by the FDA. That does not, however, mean that a drug company or manufacturer may market and promote its products for such unapproved uses. While the Department does not have the authority, nor does it seek it, to regulate the practice of medicine, it does have the responsibility to enforce the laws involving the distribution of pharmaceutical drugs in interstate commerce.

The difficult question from a law enforcement perspective is: What activity regarding off-label claims constitutes illegal promotion and merits enforcement action? It is a very important practical question with implications for:

- What drugs will be prescribed for what illnesses;
- What uses the taxpayers will pay for;
- How the government will safeguard patients; and
- How the government will maintain the integrity of the drug approval process.

The question of what constitutes illegal off-label promotion is also one that the Department believes must be answered on a case-by-case basis. There are no simple formulas that can govern enforcement decisions in this area and there is no substitute for careful, case-by-case consideration of all relevant information. That said, one way to illustrate what conduct may result in Department enforcement action is to look at the facts of matters that have resulted in prosecution. Several of the major settlements of the last few years are described below to

demonstrate how cases were evaluated and what the settlements entailed.

IV. Cephalon, Inc.

In September 2008, in the Eastern District of Pennsylvania, Cephalon, Inc., pled guilty and paid \$425 million to resolve criminal and civil charges in connection with the company's illegal promotion of three drugs—Actiq, Gabitril, and Provigil. *United States v. Cephalon, Inc.*, 2:08-CR-00598 (E.D. Pa. Sept. 29, 2008). Actiq is an extremely potent pain-killer that is delivered in the form of a lollipop. The FDA approved Actiq for use only in opioid-tolerant cancer patients and only for patients with so-called "breakthrough pain." The Information alleged that Cephalon improperly promoted Actiq for noncancer pain uses such as injuries and migraines. The Information alleged that Cephalon's management directed its sales force to visit doctors who, due to the nature of their practices, normally would not prescribe Cephalon's drugs. The visits were designed to convince the doctors to prescribe the drugs for off-label uses. For example, the Actiq label indicated that the drug was for opioid tolerant cancer patients with breakthrough cancer pain, to be prescribed by oncologists or pain specialists familiar with opioids. The Information alleged that using the mantra "pain is pain," Cephalon instructed the Actiq sales representatives to focus on physicians other than oncologists, including general practitioners, and to promote this drug for many uses other than breakthrough cancer pain.

V. Serono Laboratories

In January 2006, in the District of Massachusetts, Serono Laboratories pled guilty and paid \$704 million to resolve criminal and civil charges in connection with illegal schemes to promote and sell Serostim. *United States v. Serono Laboratories, Inc.*, 1:05-CR-10282-001-RCL (D. Mass. Oct. 18, 2005).

In 1996 the FDA granted accelerated approval for Serostim solely for use in treating Acquired Immunodeficiency Syndrome (AIDS) wasting, which at the time was one of the leading causes of

death among AIDS patients. Serostim came on the market at the same time as protease inhibitor drugs. When protease inhibitor drugs were used in combination with one another as an "AIDS cocktail," they dramatically curtailed the progress of AIDS. As a result, the incidence and prevalence of AIDS wasting began to markedly decline and the demand for Serostim dropped significantly immediately following its launch. Serono Labs then began engaging in a marketing and sales campaign to redefine AIDS wasting to create a market for Serostim.

Serono Labs pled guilty to charges that the company conspired with medical device manufacturer, RJL Sciences, to market bioelectrical impedance analysis (BIA) computer software packages for use in calculating body cell mass and diagnosing AIDS wasting. The BIA device and accompanying software devices had not been cleared by FDA for these uses. In fact, full premarket approval would have been required before the devices could have been marketed as tools for measuring body cell mass or diagnosing a disease. Serono Labs conspired with RJL to increase the market for the devices/software in order to increase the market for Serostim.

Serono Labs employees also directly administered BIA tests to patients to induce doctors to prescribe Serostim and to get Medicaid agencies and other payers to reimburse for the drug.

Additionally, Serono Labs pled guilty to kickback violations resulting from offering physicians an all expense-paid trip to a medical conference in Cannes, France. In return, the doctors were to write up to 30 new prescriptions of Serostim, which cost \$21,000 per course of treatment, for a total value to Serono of \$630,000 per doctor.

Finally, in 2008 the former Medical Director of Serono Laboratories pled guilty to three counts of causing the dissemination of the adulterated computer software devices used to interpret the BIA test results in order to diagnose AIDS wasting and to increase sales of an AIDS wasting drug. *United States v. Muurahanian*, 1:08-CR-10182-JGD (D. Mass. Jun. 19, 2008). However,

four other former Serono executives were acquitted in Boston on various conspiracy and kickback charges.

VI. Other cases

Bristol-Meyers Squibb's drug, Abilify, was approved for treatment of adult schizophrenia and bipolar disorder. In September 2007, in the District of Massachusetts, Bristol-Myers agreed to pay \$515 million to settle civil allegations that it promoted the drug for pediatric use and dementia-related psychosis. Press Release, U.S. Department of Justice, Bristol-Myers Squibb to Pay More than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing (Sept. 28, 2007), available at http://www.usdoj.gov/opa/pr/2007/September/07_civ_782.html.

In February 2006 Eli Lilly pled guilty in connection with its illegal promotion of Evista. In addition to the criminal plea, Lilly agreed to settle civil FDCA liabilities by entering into a consent decree of permanent injunction. Lilly paid a total of \$36 million to settle the criminal and civil charges. *United States v. Eli Lilly and Co.*, IP05-206-CR-01 (S.D. In. Jan. 26, 2006).

Purdue Pharma's drug, OxyContin, was approved for management of severe pain in specific instances. In the Western District of Virginia, in May 2007, Purdue pled guilty to felony misbranding charges relating to misrepresentations it made to health care providers that OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause withdrawal problems than other pain medications. Three current and former Purdue Pharma executives also pled guilty to misdemeanor counts of misbranding. Purdue paid \$634.5 million to settle the allegations. *United States v. The Purdue Frederick Co.*, 1:07-CR-00029-JPJ-1 (W.D. Va. July 23, 2007).

Pharmacia & UpJohn Co. LLC, a subsidiary of Pfizer, entered a deferred prosecution agreement for its illegal promotion of Genotropin. Genotropin was approved for certain specific growth hormone deficiencies. In April 2007, in the District of Massachusetts, Pharmacia &

UpJohn paid \$15 million to settle allegations that it promoted the drug for anti-aging, cosmetic use, and athletic performance enhancing purposes. Another Pfizer subsidiary, Pharmacia & UpJohn Co., Inc., pled guilty to violations of the Anti-Kickback Act and paid a criminal fine of \$19.68 million. *United States v. Pharmacia & UpJohn Co.*, 1:07-CR-10099-RGS (D. Mass. Apr. 2, 2007).

InterMune's drug, Actimmune, was approved for a narrow set of disorders of the immune system. In October 2006, in the Northern District of California, Intermune paid \$36.9 million to settle criminal and civil allegations that it promoted the drug for an incurable lung scarring condition. *United States v. Intermune, Inc.*, 3:06-CR-00707-MHP (N.D. Cal. Oct. 26, 2006).

In August 2006, in the District of Massachusetts, Schering-Plough Corporation paid a total of \$435 million to resolve criminal charges and civil liabilities in connection with illegal sales and marketing programs for two drugs:

- Temodar for use in the treatment of brain tumors and metastases; and
- Intron A for use in treatment of superficial bladder cancer and hepatitis C.

Neither drug has been approved for these conditions. *United States v. Schering Sales Corp.*, 1:06-CR-10250-PBS (D. Mass. Aug. 29, 2006).

As this article notes, this is a very active area of law enforcement. These cases are an excellent example of Main Justice and United States Attorneys' offices working together as a prosecution team. OCL stands ready, willing, and able to assist United States Attorneys' offices around the country in investigating and prosecuting violations of the Food, Drug, and Cosmetic Act and other consumer protection statutes.

❖ ABOUT THE AUTHOR

❑ **Eugene Thirolf** has been the Director of the Office of Consumer Litigation since 1992. Mr. Thirolf personally supervised all of OCL's work in the cases reported here. Mr. Thirolf has done very different things during his Department of Justice career. He investigated and litigated cases involving Nazis and Nazi collaborators who illegally immigrated to the United States. He was a prosecutor with the Justice Department's General Litigation and Legal Advice Section. He has prosecuted counterfeiters and black market traffickers of pharmaceuticals in addition to legitimate pharmaceutical and medical device manufacturers.✉

Prosecuting Organizations in Human Growth Hormone (hGH) Cases

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I. Introduction

This article focuses on factors prosecutors must consider when charging and prosecuting manufacturers, importers, distributors, corporate entities, pharmacies, pharmacists, sales representatives, and doctors of criminal offenses associated with illegal human growth hormone (hGH).

II. Background surrounding legal and illegal uses of hGH

Hardly a week goes by that the news is not riddled with stories involving the misuse of hGH by athletes, bodybuilders, actors, and people just seeking a "fountain of youth." In recent years, antidoping scandals have affected the way almost all professional and amateur athletic endeavors are viewed. Athletes look to performance enhancing drugs in an effort to gain an edge over their competition. They weigh the benefit of athletic accolades favorably against the shame associated with getting caught in a doping scandal. Many of these athletes face criminal prosecution for conduct associated with the illicit use of performance enhancing drugs, including anabolic steroids and hGH.

Body builders often use hGH because competitors believe that, when combined with anabolic steroids, it will rapidly build muscle mass and reduce the amount of time needed for the body to heal itself. Athletes, such as bodybuilders, who are subject to antidoping testing have been keenly aware that prior to this year no accurate test existed to confirm its use. It

is, therefore, an ideal substance to escape oversight and scrutiny from antidoping officials.

In recent years, participants in the antiaging movement have embraced the use of hGH to slow the affects of aging on the human body. Claims of decreased pain and increased strength and stamina are not uncommon. Users typically try to retrofit hGH's antiaging qualities into a very narrow use that the Food and Drug Administration (FDA) has approved relating to the treatment of rare pituitary tumors. Despite the claims of legitimacy from this sector of users, however, a generalized antiaging application for hGH is not recognized as safe or FDA approved. As discussed below, any "off-label" or unapproved uses of hGH violate federal statutes.

While hGH may benefit users, its improper or unregulated use also carries numerous risks. Clinical research has not identified all of the side effects, as researchers have completed only a few studies into the long-term effects of hGH on the body. Researchers have linked the use of hGH with an increased chance of developing diabetes, arthritis, and carpal tunnel syndrome. More dramatically, authorities fear an increased risk of stimulating the growth of cancer cells. Additionally, hGH is known to carry contaminants. Those who dispense unapproved and untested hGH may also be dispensing bacteria, yeast toxins, or other substances to which a patient may show counter indication. For this reason, the FDA inspects manufacturing facilities as part of its oversight authority.

III. Common sources of hGH

A. FDA approved manufacturers and legal uses of hGH

There are legitimate manufacturers and distributors of hGH operating in the United States. Some domestic manufacturers produce a synthetic hGH called recombinant hGH, which acts just like the hGH produced naturally in a healthy human body. These companies comply with the application and approval process mandated by the Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 110-243, ch. 675, 52 Stat. 1040 (codified in scattered sections of 21 U.S.C.). The FDA regulates the approval process for the manufacture and use of hGH in the United States pursuant to the FDCA, and recognizes only six narrowly defined indications for hGH in this country. Those indications are for the following genetic or medical conditions:

- Hormonal deficiency that causes short stature in children;
- Long-term treatment of growth failure due to lack of exogenous growth hormone secretion;
- Long-term treatment of short stature associated with Turner syndrome;
- Adult short bowel syndrome;
- Adult deficiency due to rare pituitary tumors or their treatment; and
- Muscle-wasting disease associated with HIV/AIDS.

Therefore, the "off-label" or unapproved uses of hGH, such as bodybuilding or antiaging, are illegal.

B. Overseas manufacturers not approved by FDA

A significant regulatory and safety problem arises when hGH is produced overseas in places such as China. Foreign manufacturers of hGH must obtain FDA approval prior to their product becoming legal for distribution in the United States. To date, there are no FDA-approved Chinese manufacturers of hGH because

there have been no inspections of manufacturing facilities in China, and no new drug applications by any Chinese hGH manufacturers have been filed with and approved by the FDA. Therefore, any Chinese hGH that enters the United States is imported and distributed "contrary to law," as it constitutes contraband *ab initio*. Any practitioner who dispenses Chinese hGH, even for approved uses, violates several federal criminal statutes, as discussed herein.

IV. Target defendants: Prosecutorial considerations

Prosecutions of illicit distribution of hGH may range from an individual distributor at a local gym to mass disbursal facilitated by business entities and pharmacies. Cases centered on sophisticated distribution scenarios will almost always touch upon both the complex and simple case scenarios. A prosecutor will likely discover a vertical chain of distribution from the manufacturer down to the eventual end user of the product. Typically, an overseas manufacturer produces the hGH and then ships it to distributors in the United States. The distributor then sells the hGH to its customers, including pharmacies. The pharmacies then advertise and market the hGH to doctors and patients domestically.

Profit is substantial in every step of the distribution chain, because the markup on hGH is so great and the dosages involve such small amounts. An end user can expect to pay around \$55,000 for one gram of hGH, a profit margin exceeding that of crack cocaine. The standard dosage of hGH for children is higher than that for an adult, about 60-100 micrograms per kilogram of body weight per day. The standard dosage of hGH for adults is 7-8 micrograms per kilogram of body weight per day. The appropriate dosage decreases as a user ages, however, because of the potential side effects.

A. The overseas manufacturer

Due to its limited resources and the complexity of the global marketplace, the FDA rarely inspects foreign pharmaceutical manufacturers. As mentioned in section III.B of

this article, the FDA has never conducted an inspection of any Chinese hGH manufacturing plant. Therefore, any drugs manufactured in China that are subject to the application and approval process of the FDCA are not FDA approved and constitute contraband when they are brought into the United States. This circumstance is particularly troubling given that counterfeit pharmaceuticals from foreign countries are flooding the United States market. Many of these drugs have no active pharmaceutical ingredients at all. Overseas manufacturers often contract with importers from the United States to deliver cheap, unapproved, and uninspected pharmaceuticals to distribution points inside the United States or directly to users through Internet orders.

B. The importer/distributor

As with traditional commerce, importers play a significant role in the distribution chain of pharmaceuticals in the United States. Internet commerce enables importers to contract with more potential manufacturers throughout the world. Because of the profit motive associated with this business, an importer will often look for the cheapest product on the market. Some importers intentionally mislead authorities as to the true nature of the substance in order to avoid detection by import officials. To the untrained eye many pharmaceuticals look identical to otherwise legal substances. These substances are mislabeled to avoid confiscation as they enter the United States. Coupled with the obvious overwhelming amount of commerce that enters the United States every day, it is not surprising that so much international, uninspected hGH enters the United States illegally.

C. The pharmacy-corporate criminal, civil, and administrative liability

Pharmacies, including Internet pharmacies, act as legitimate retailers of FDA-approved hGH that they dispense legally. Many such online or catalog pharmacies conduct themselves in an ethical and responsible way, but others choose to skirt the law in order to bring a cheaper product to the market. These rogue pharmacies are motivated

by greater profit, not the safety of the product they sell.

Prosecutors must understand the hierarchy within a target pharmacy in order to determine who makes the contractual decisions relating to the sources of hGH, whether from overseas or importers in the United States. Pharmacies in the United States come in all different sizes and vary in terms of corporate complexity. They range from the nationally recognized chains to Internet pharmacies to the local mom and pop storefront pharmacies. Regardless of their size or structure, all pharmacies have someone within their structure directly responsible for obtaining the pharmaceuticals they sell. That person, whether a pharmacist or not, is a critical link in the evidence necessary to prove the knowledge others may have about the legality of the substances dispensed, including hGH.

V. The pharmacy as a business organization

A. Corporate criminal exposure

Like the manufacturer and importer, both the pharmacy that sells illicit hGH and its owners may have criminal, civil, and administrative exposure. Corporate criminal exposure is subject to the *Principles of Federal Prosecution of Business Organizations* that was incorporated into the United States Attorneys' Manual (USAM) in August 2008. Section 9-28-300 of the USAM enumerates a nonexhaustive list of considerations for prosecutors of business entities:

- The nature and seriousness of the offense, including the risk of harm to the public, and applicable policies and priorities, if any, governing the prosecution of corporations for particular categories of crime;
- The pervasiveness of wrongdoing within the corporation, including the complicity in, or the condoning of, the wrongdoing by corporate management;
- The corporation's history of similar misconduct, including prior criminal, civil, and regulatory enforcement actions against it;

- The corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate in the investigation of its agents;
- The existence and effectiveness of the corporation's pre-existing compliance program;
- The corporation's remedial actions, including any efforts to implement an effective corporate compliance program or to improve an existing one, to replace responsible management, to discipline or terminate wrongdoers, to pay restitution, and to cooperate with the relevant government agencies;
- The collateral consequences, including whether there is disproportionate harm to shareholders, pension holders, employees, and others not proven personally culpable, as well as impact on the public arising from the prosecution;
- The adequacy of the prosecution of individuals responsible for the corporation's malfeasance; and
- The adequacy of remedies such as civil or regulatory enforcement actions.

Prosecutors must apply these considerations, as well as the other guidance provided by the USAM, when determining whether to subject the pharmacy under investigation to criminal, civil, or administrative penalties.

The consequences of a criminal prosecution could be catastrophic to a pharmacy or business entity. Aside from a potential fine, the Drug Enforcement Administration may bar a pharmacy convicted of a felony offense from further dispensing controlled substances. The entity could also be subject to exclusion from participation in federal programs like Medicare that are financial mainstays of the business. If the business is a publicly-traded entity, the prosecution will impact shareholders who may not have been aware of any wrongdoing. In short, a criminal prosecution may be a *de facto* death penalty to a business entity.

B. Pharmacists—individual criminal and professional liability

In relatively small pharmacy operations, the pharmacist in charge may also be the owner of the business entity. In larger operations, the pharmacy under investigation could be a small subsidiary of a much larger business entity. Under either scenario, pharmacists are subject to the rules, regulations, and ethical responsibilities promulgated by state licensing boards. In addition to a one-time fine or imprisonment, a conviction may also result in sanctions from their licensing board. Because pharmacists are a necessary component to the large scale distribution of contraband hGH, their prosecution is a key choke point to deter the distribution of illicit hGH and steroids. The deterrent effect of prosecuting professional, licensed pharmacists is substantial, and criminal and administrative exposure may compel these professionals to cooperate against other more culpable actors.

Pharmacists are key to illicit hGH distribution cases because they are in the best position to stop the distribution of hGH for off-label, illegal uses.

- They are familiar with the rules and regulations relevant to dispensing drugs;
- They are in a position to examine the dispensing histories for patients;
- They review prescriptions and are often able to determine whether they are valid; and
- They deal directly with physicians or patients.

Most pharmacists are able to determine off-label usage by reviewing the dispensing history for patients. In an hGH case, a pharmacist can determine if a patient's dispensing history is within the approved uses. Further, a pharmacist usually has the ability to contact physicians to confirm the validity of prescriptions that appear suspect. Like other professionals, pharmacists are acutely aware of the manner in which users abuse the drugs they dispense. The massive profit potential of off-label hGH distribution should not taint their professional judgment.

C. Sales representatives

Sales representatives are often paid on a commission basis or have an incentive-structured compensation package. Their motivation in selling the company's product is almost entirely based on selling as much as possible in order to maximize their income. The representations they make to potential customers may bind the company and may constitute admissions. Advertising materials the sales representatives use to attract business are often, but not always, sanctioned by officers of the distributor. The representations used to induce new customers are valuable evidence in framing a fraud theory of criminal liability. Additionally, sales representatives are well trained and know the approved uses for hGH. Lastly, because sales representatives rely on guidance from persons with technical expertise, like pharmacists, the information they provide regarding communications with persons in the business entity will help establish the knowledge and intent elements of federal violations by both individuals and businesses.

D. Legitimate customers: doctors and patients

Physicians are unique in the distribution chain because they can dispense hGH, or direct that pharmacists do so, via prescriptions. Doctors have criminal liability if they knowingly dispense or aid the dispensing of unapproved hGH for unapproved uses or without a valid prescription. Like their patients, however, they may be victims of misrepresentations by the pharmacy or distributor if the hGH dispensed is not FDA approved.

Patients are rarely the focus of federal prosecution. If they are using the hGH for any of the six approved purposes, they are unlikely to possess the sophistication to distinguish between legal and illegal hGH. The end user usually relies on the expertise of professionals like pharmacists and doctors to provide legal, approved pharmaceuticals. Unfortunately, patients who unwittingly use illegal hGH will not realize the benefits of the legitimate substance if they are taking a subpotent, contaminated, or counterfeit

drug. The danger that the unapproved substance they are taking may actually cause them harm is substantial.

E. Illegitimate customers: Athletes, bodybuilders, and the antiaging movement

Off-label use of hGH is rampant in the United States. Illegitimate users obtain their seemingly unlimited supply via domestic and foreign Internet distributors, domestic importers and distributors, and otherwise legitimate pharmacies. The prescriptions that illegal users obtain may be invalid for a variety of reasons. Physicians may not issue prescriptions without an examination or valid physician-patient relationship. Forgery and fraud are also rife within this sector of users. Although they assume a greater risk than the patients who use hGH for legitimate on-label purposes, illegitimate customers are victims if they believe they are buying FDA-approved hGH, when in truth they may receive unapproved hGH that is contaminated, subpotent, or counterfeit. These customers are valuable sources of information regarding the marketing and representations made by salesmen and distributors. Of course, these types of victims are less sympathetic to a jury and will be subject to great scrutiny on cross-examination.

VI. The indictment: Charging the case

A. Distribution and possession with the intent to distribute hGH (21 U.S.C. § 333(e))

There are a number of similarities between controlled substances cases and hGH cases. Most obvious is the fact that steroid use and illicit hGH use go hand-in-glove in the athletic arena. A prosecutor may see both substances intertwined in the facts of a particular case. It is important to note, however, that while anabolic steroids, including testosterone cypionate and testosterone prepionate, are Schedule III controlled substances subject to the Controlled Substances Act, Pub. L. No. 91-513, 84 Stat. 1242 (1970) (codified in scattered sections of 21 U.S.C.), hGH is not a listed controlled substance, and the FDCA

primarily governs its illegal distribution. A close examination of the provisions of each Act dealing with illegal distribution of the respective substances reveals striking similarities between the provisions. Such similarities are important because the case law relative to the Controlled Substances Act is well developed in comparison to that of the relevant portions of the FDCA.

Both provisions recognize a felony criminal violation for either the distribution or possession with the intent to distribute their respective illicit substance. The main distinction between the two is in the defenses for a violation. Whereas the Controlled Substances Act has separate provisions that legitimize distribution by approved persons (doctors and pharmacies) pursuant to valid prescriptions, the FDCA incorporates its "safe harbor" within the same provisions defining the violation. Prohibited Distribution of Human Growth Hormone, 21 U.S.C. § 333(e) (2003), provides that:

[W]hoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 . . . and pursuant to the order of a physician, is guilty of [prohibited distribution of human growth hormone]. . . .

The term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

The elements of distribution or possession with the intent to distribute hGH are:

First: the defendant knowingly or intentionally distributed or possessed with the intent to distribute human growth hormone for use in humans; and

Second: the distribution or possession with the intent to distribute human growth hormone in humans was (a) not for the treatment of a disease or other recognized medical condition as authorized by the Secretary of Health and Human Services, or

(b) was not approved by the Secretary of Health and Human Services (or the FDA) pursuant to the application and approval process of 21 U.S.C. § 355, or was not (c) pursuant to a valid order of a physician.

With the exception of the defenses already discussed, this provision tracks the same statutory language of Title 21 U.S.C. §§ 841-843 (2006) of the Controlled Substances Act. The elements of the two offenses are nearly identical.

B. The safe harbor requirements as a defense

There are three conditions that must be met in order for a defendant to avail himself of the "safe harbor" provision of the statute.

- First, he must possess the hGH for one of the six approved uses;
- Second, the FDA must have approved the specific hGH in question, pursuant to 21 U.S.C. § 355 (relating to the application and approval of new drugs); and
- Third, the defendant must have dispensed the hGH pursuant to the order of a physician.

As discussed above, any off-label use of the hGH bars the application of the safe harbor provision.

The second condition requires that the FDA approve the particular kind of hGH at issue. This means that the prosecutor must investigate its origin to determine whether it complies with the FDCA application and approval process for new drugs. Many overseas manufacturers, including Chinese manufacturers, produce and distribute unapproved hGH that is not in compliance with the FDCA's application and approval process.

The third prong of the safe harbor provision requires an "order of a physician," i.e., a valid prescription. In order to be valid, a prescription must include a licensed doctor's order for medicine that an actual patient really needs. A prescription is not valid if the doctor fails to examine or consult with the patient. The examination or supervision must involve active, good-faith participation in the doctor's professional capacity. A prescription that fails to

meet this standard is merely "a phony piece of paper signed by a doctor for drugs." *United States v. Nazir*, 211 F. Supp. 2d 1372, 1375-77 (S.D. Fla. 2002). Open purchase agreements, often referred to as stocking agreements, are not valid prescriptions and cannot in good faith be an "order of a physician" as the statute envisions.

C. The "compounding" defense

In recent years, compounding pharmacies have attempted to rely on state definitions to carve out defenses to the FDCA. They assert that the Act excludes compounded drugs from the application and approval process of the Act. *See* 21 U.S.C. § 353(a) (2004). They also turn to broad state definitions that equate compounding to, among other things, "labeling" or "repackaging." However, the United States Supreme Court ruled on what constitutes "compounding" under the FDCA in *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002). The Court explained that

[d]rug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product.

Id. at 360-61; *see also Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383 (5th Cir. 2008); *United States v. Livdahl*, 459 F. Supp. 2d 1255, 1262 (S.D. Fla. 2005). The *Livdahl* court dismissed a pharmacy's argument that state laws should define the compounding process. *Id.* at 1264. In the *Med. Ctr. Pharmacy v. Mukasey* case, the Fifth Circuit recognized that compounded drugs are new drugs, subject to the application and approval process of the FDCA. In practice, prosecutors must examine whether the final drug product is compounded pursuant to the federal definition. If it is not compounded, no further analysis is necessary. Compounded concoctions are subject to the new drug provisions in the FDCA, however, and may prompt further

prosecutorial action. *Med. Ctr. Pharmacy*, 536 F.3d at 395-97.

D. Facilitation of the sale of smuggled goods or receiving smuggled goods (18 U.S.C. § 545) (2006)

In order to fully assess the criminal exposure of persons in the chain of distribution, prosecutors must be wary of the country of origin of the hGH at issue. If the hGH violates provisions of the FDCA, including §§ 331(a) (prohibiting the introduction into interstate commerce of a misbranded drug), 352(f)(1) (relating to causing the introduction into interstate commerce of a misbranded drug in that it failed to bear adequate directions for use), 331(d) (prohibiting the introduction into interstate commerce of an article that is in violation of § 355), and § 355 (prohibiting the introduction into interstate commerce of a new drug without proper application and approval), then its importation into the United States is "contrary to law" under Title 18 U.S.C. § 545 (2006). The introduction of merchandise into interstate commerce is "contrary to law" when it is "illegal merchandise" by its very nature. *See United States v. Garcia-Paz*, 282 F.3d 1212, 1214 (9th Cir. 2002); *see also United States v. Mitchell*, 39 F.3d 465, 468-69 (4th Cir. 1994). Merchandise is "illegal" when the merchandise itself violates state or federal law, including 21 U.S.C. §§ 331(a), 352(f)(1), 331(d), or § 355, as set forth previously.

Defendants violate the smuggling statute when they facilitate the sale of a smuggled good or receive a smuggled good that has been brought into the United States "contrary to law." It is hard to imagine how any of the individuals in the distribution chain of contraband hGH would not have some criminal exposure if they knew the hGH they distributed was from a country of origin, like China, that has no manufacturers that make FDA-approved hGH.

The elements of Facilitating the Sale of Smuggled Goods (or Receiving Smuggled Goods) in violation of 18 U.S.C. § 545 (2006), are as follows:

- First: hGH was imported or brought into the United States contrary to law in that it violated one or more of the federal statutory provisions noted above; and
- Second: the defendant received, bought, sold, or facilitated the sale of hGH knowing that it had been imported or brought into the United States contrary to law.

E. Entry of goods by means of false statements (18 U.S.C. § 542) (1996)

Prosecutors should also investigate the means by which contraband hGH is imported. Manufacturers and importers of foreign-made hGH may have brought the hormone into the United States by means of false declarations or statements. Additionally, persons in the distribution chain make false statements about the true nature of drugs and pharmaceuticals to avoid detection and confiscation of their contraband by Immigration and Customs Enforcement (ICE) inspectors and FDA inspectors. Section 542 also provides that defendants who knowingly receive smuggled goods that entered the United States by means of false statements are subject to criminal liability. Similar to narcotics cases, a prosecutor will establish a continuing criminal business relationship between suspects, and thus will likely develop evidence of knowledge as to the manner in which hGH was brought into the country. A thorough investigation will reveal defendants who receive contraband hGH with knowledge of how it was brought here at each step of the distribution chain.

The elements of Receiving Smuggled Goods that Entered by Means of False Statements in violation of Title 18 U.S.C. § 542 are as follows:

- First: The defendants received hGH in the United States;
- Second: The defendants knew that the hGH should have been declared or reported to customs authorities as required by law;
- Third: The defendants acted knowingly; and
- Fourth: The defendants did something which was a substantial step toward receiving the hGH.

F. Mail fraud, wire fraud, and health care fraud (18 U.S.C. §§ 1341 (2008), 1343 (2008) and 1347 (1996))

Prosecutors should consider the federal fraud statutes to establish criminal liability in most large scale distributions of hGH, especially if the distribution chain includes established businesses like corporate distributors and pharmacies. When considering whether to charge any of the fraud statutes in an indictment, a prosecutor should ask some preliminary questions before making a final decision about the use of the mail fraud, wire fraud, or health care fraud statutes. Preliminary determinations should include the hGH's origin, entry, and FDA approval status, as discussed above. Specific to §§ 1341, 1343, and 1347, the representations distributors made to customers, the FDA, or health care benefit programs regarding the legality of the particular hGH, and a determination if any of the statements were patently false or contained material omissions may reveal additional wrongdoing chargeable under these provisions. Any investigation should also include how defendants used mail or wire systems to execute the scheme and whether the alleged victims were participants in the scheme.

Cases involving large, established corporate entities or pharmacies will likely reveal false representations to customers, such as physicians and their patients. Usually, the persons who devise and implement the scheme to defraud profit the most from the fraudulent conduct, and representations made on behalf of corporate entities by officers or sales representatives may be imputed to the business entity. In such cases, evidence of profit motive will explain the relationships between the individuals and the business entity.

G. Conspiracy (18 U.S.C. § 371) (1994)

The general conspiracy statute found in Title 18 U.S.C. § 371 is an ideal prosecutorial tool in multidefendant prosecutions involving individuals and businesses along a vertical chain of distribution of hGH. In all but the Tenth Circuit, the elements of the offense of conspiracy are as follows:

- First: The defendant agreed with at least one other person to violate the law;
- Second: One of the conspirators engaged in at least one overt act furthering the conspiracy's objective;
- Third: The defendant knew the essential objective of the conspiracy; and
- Fourth: The defendant knowingly and voluntarily participated.

In the prosecution of hGH cases involving multiple targets or defendants, prosecutors can apply the general conspiracy statute to the offenses discussed in this article, including:

- The Distribution or Possession with the Intent to Distribute Human Growth Hormone (Title 21 U.S.C. § 333(e)) (2003);
- The Facilitation of the Sale (or Receipt) of Smuggled Goods (Title 18 U.S.C. § 545) (2006);
- The Entry of Merchandise into the United States by Means of False Statements (Title 18 U.S.C. § 542) (1996);
- Health Care Fraud (Title 18 U.S.C. § 1347) (1996);
- Mail Fraud (Title 18 U.S.C. § 1341) (2008); and
- Wire Fraud (Title 18 U.S.C. § 1343) (2008).

However, the maximum statutory penalty for the conspiracy charge, 5 years imprisonment, may be substantially less than the underlying substantive charges. Because hGH is not classified as a controlled substance, the specific conspiracy statute in the Controlled Substances Act, found at Title 21 U.S.C. § 846 (1998), does not apply to these types of cases.

H. Other offenses: Theories of criminal liability

- **Aiding and abetting.** Similar to the general conspiracy statute, the underlying criminal offenses discussed above go hand in glove with the aiding and abetting statute found in Title 18 U.S.C. § 2 (1951). Simply stated, the

law extends criminal liability to those who help in the commission of a substantive offense.

- **Accessory after the fact.** A target may also incur criminal liability by being an accessory after the fact, pursuant to Title 18 U.S.C. § 3 (1994), if he obstructs justice by assisting another person who committed the underlying crime, in order to hinder or prevent that person's apprehension or punishment.
- **Misprision of a felony.** Title 18 U.S.C. § 4 (1994) recognizes an offense of concealing or failing to notify authorities of the commission of a federal felony. Individuals, given the opportunity, must report the commission of a federal felony to an appropriate authority. Pharmacies and their pharmacists cannot simply bury their heads in the sand and not report federal criminal violations.
- **Money laundering.** Title 18 U.S.C. §§ 1956 (2008) and 1957 (2006). Many of the above-discussed statutes constitute specified unlawful activity (SUA) that may give rise to criminal liability pursuant to the money laundering statutes. Charging money laundering facilitates criminal forfeiture of the proceeds from criminal activity, as well as any property, real or personal, involved in the offense. Also, a finding of guilt on a money laundering count could provide an enhancement at sentencing. Because of recent developments in money laundering law, prosecutors must be prepared to prove the proceeds from the SUA were profit. *United States v. Santos*, 128 S.Ct. 2020 (2008).
- **Other provisions of the FDCA.** Title 21 U.S.C. § 331 (2007) contains a list of violations that attach criminal liability, including §§ 331(a) (prohibiting the introduction into interstate commerce of a misbranded drug) and 331(d) (prohibiting the introduction into interstate commerce of an article that is in violation of § 355) (2008) (relating to the application and approval process for new drugs). These are misdemeanor offenses unless they involve an

"intent to defraud or mislead," in which case the additional element makes them 3-year maximum felonies. Title 21 U.S.C. § 333 (2003).

VII. Criminal and civil forfeiture

Most of the criminal statutes discussed above have associated forfeiture provisions. However, because some substantive offenses offer only limited forfeiture, prosecutors must ensure that the criminal charges address the entire criminal activity and that the criminal forfeiture encompasses both "facilitation property" and "proceeds" of the criminal activity, along with the forfeiture of any contraband. Although criminal forfeiture may create joint and several liability, codefendants are entitled to credit for the amounts paid by others, not to exceed the total forfeiture award. *See United States v. Hurley*, 63 F.3d 1 (1st Cir. 1995); *United States v. Cleveland*, 1997 WL 602186 *3 (E.D. La. Sept. 29, 1997) (unpublished) ("the United States . . . may not recover the full amount of the forfeiture proceeds from both defendants, although it may recover the entire amount from either of them."); *United States v. McCarroll*, 1996 WL 355371 *9 (N.D. Ill. June 25, 1996) (unpublished) ("although the government may only collect once on a forfeiture order, it may collect the entire amount from anyone who is held jointly and severally liable."); *United States v. Loren-Maltese*, 2003 WL 291910 *2 (N.D. Ill. Feb. 10, 2003) (unpublished) ("the defendant will be given an appropriate credit for amounts recovered from any jointly and severally liable codefendants.").

Prosecutors must also be prepared to address civil forfeiture as an alternate means of obtaining a just result. Civil forfeiture allows the government to address business organization misconduct short of a criminal indictment and felony conviction that may close the business doors.

VIII. Sentencing

The United States Sentencing Guidelines [hereinafter Guidelines] do not directly address the computation of a sentence for the distribution or possession with the intent to distribute hGH because hGH is not a controlled substance subject to the computations in the Guidelines. U.S. SENTENCING GUIDELINES MANUAL § 2D1.1 (2006). If smuggling crimes are part of the theories of criminal liability, however, prosecutors should argue that the applicable calculations are those associated with smuggling crimes. U.S. SENTENCING GUIDELINES MANUAL § 2T3.1 (2006). Although hGH does not have a duty associated with it, U.S. SENTENCING GUIDELINES MANUAL § 2T3.1 cmt. n.2 (2006), allows for an alternate measure of the "duty" evaded to be computed by assessing 25 percent of the fair market value of the smuggled items. In *United States v. Dall*, 918 F.2d 52, 54 (8th Cir. 1990), the Eighth Circuit upheld a sentence calculated under Note 2. In that case, the defendant pled guilty to smuggling an animal drug (chloramphenicol, an antibiotic) into the United States in violation of the FDCA. *Id.* at 53. The defendant declared the drugs and paid a duty on them, but he violated the law because, under the FDCA, the drugs were classified as adulterated. *Id.* The court did not address the defendant's argument that the drugs were not harmful, but it held that his sentence, based on Note 2, was reasonable. *Id.* at 54. The fair market value of the hGH, an extremely high-priced substance, will result in a substantial base offense level under this theory.

As with other offenses, the Guidelines adjustments to the base offense level apply. For example, if the crimes of conviction involve multiple entities with different roles in the offense, a role adjustment to the base offense level may be warranted. *See* U.S. SENTENCING GUIDELINES MANUAL § 2T3.1 (2006). Similarly, a money laundering conviction results in a 2-point offense level increase pursuant to U.S. SENTENCING GUIDELINES MANUAL § 2S1.1(b)(2) (2006). The final sentence in the prosecution of these cases will be driven in large part by the

offenses of conviction, which in turn are driven by the offenses of indictment.

IX. Conclusion

Prosecutors must use every available criminal theory of prosecution to combat the mass distribution of illegal hGH. The criminal organizations that distribute hGH, like those of traditional drug prosecutions, vary in size and complexity. These criminal organizations often involve otherwise legitimate businesses and individuals to distribute illicit hGH for huge profits. The charging decisions in these prosecutions will greatly influence the sentences in these cases and the deterrent effect on society.❖

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Double Secret: The Unique Confidentiality of Substance Abuse Medical Records

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I. Introduction

When prosecuting drug cases or health care fraud cases, the confidentiality of the underlying medical records can be one of the thorniest problems. In that regard, perhaps the most overlooked issue involves the unique confidentiality rules for substance abuse medical records, which are governed by 42 C.F.R. Part II. The danger of noncompliance is particularly acute since violations may be punished by criminal fines. 42 C.F.R. §§ 2.3, 2.4 (citing 42 U.S.C. § 290ee-3(f), 42 U.S.C. 290dd-3(f)).

The one thing to remember about the confidentiality of substance abuse medical records is that they are "double secret;" in other words, the unique confidentiality rules are *in addition* to those promulgated as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. Part 164. Over the past several years, prosecutors have been lulled into a false sense of security because grand jury subpoenas, Inspector General (IG) subpoenas, and search warrants are routinely used to trump HIPAA's requirements. 45 C.F.R. § 164.103. Those time-honored techniques, however, will not succeed with substance abuse records. Instead, grand jury subpoenas and search warrants are typically the beginning, not the end, of the process.

For those who prosecute drug and health care fraud cases, another important development is that substance abuse treatment medical records are no longer limited to methadone clinics and pain specialists. Instead, as a result of recent statutory and regulatory amendments, general practice doctors may treat substance abuse patients in an office-based setting with drugs such as Suboxone/Buprenorphine, which are typically used for heroin addiction. 21 C.F.R. Parts 1301 and 1306. The growing use of office-based substance abuse treatment means that the unique confidentiality rules apply in settings that, until recently, were only protected by HIPAA.

Strategic considerations are also important because the confidentiality protections attach to the records themselves, which triggers compliance considerations every time there is a redisclosure. Indeed, the records must be accompanied by a formal notice that prohibits redisclosure unless specifically authorized by the regulation. 42 C.F.R. § 2.32. That requirement can complicate an investigation as access to (and use of) the records necessarily expands. *See, e.g.*, 42 U.S.C. § 290dd-2(d) (the substance abuse confidentiality restrictions apply even after the individual ceases to be a substance abuse patient).

This article provides an overview of when you should worry about the confidentiality of substance abuse records, how you may solve the problem, and what strategies you may employ. The article concludes with a step-by-step case study of a parallel criminal and civil health care fraud case that illustrates how the regulations apply at each stage of an investigation and prosecution. The case study is based on the parallel investigation and prosecution in *United States v. Shinderman*, 2006 WL 522105 (D. Me. Mar. 2, 2006) (Recommended Decision), *affirmed*, 432 F.Supp.2d 149, *affirmed*, 515 F.3d 5, 11-13 (1st Cir. 2008), and *United States v. CAP Quality Care, Inc.*, 486 F. Supp.2d 47 (D. Me. 2007).

II. When you should worry

Since the substance abuse confidentiality rules are challenging and only apply in a limited number of cases, you should begin by considering whether, in your particular case, you can rule them out. It is best to begin by considering that the substance abuse confidentiality rules only apply to two categories of medical records. Accordingly, as a prosecutor, if the records you seek do not fall within either category, you do not have to worry about 42 C.F.R. Part II.

The first category involves medical records for "alcohol abuse," which the regulations define broadly to include "the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user." 42 C.F.R. § 2.11 (definition of alcohol abuse). Practically speaking, that covers a wide variety of treatment for alcohol-related problems. Fortunately, however, federal drug and health care prosecutions rarely involve requests for alcohol abuse treatment records.

For most prosecutions, the far more important category involves medical records for drug abuse, which the regulations define as the "use of a psychoactive substance for other than medicinal purposes." 42 C.F.R. § 2.11 (definition of drug abuse). That definition is sufficiently broad to cover a wide variety of cases that are routinely prosecuted in federal court. Moreover, the definition creates somewhat of a Catch-22 for the prosecutor since it defines drug abuse in terms of the purpose behind the patient's use of drugs but that purpose is virtually impossible to discern without access to the requested records. Accordingly, you need to err on the side of caution and begin your case with the assumption that the patient abused drugs for a reason other than medicinal purposes.

Even if the requested records fall within either of those two categories, the confidentiality rules only apply if the practitioner or facility "holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment." 42 C.F.R. § 2.11 (definition of a program). Thus, the records of a primary care doctor who does not hold himself out as providing

alcohol or drug abuse treatment would not be covered. Similarly, the confidentiality rules do not apply to hospitals (defined as general care facilities) except as to an identified unit within the hospital that has a primary function of providing substance abuse diagnosis, treatment, or referral. 42 C.F.R. § 2.11 (definition of program); *Ctr. for Legal Advocacy v. Earnest*, 320 F.3d 1107 (10th Cir. 2003) (the substance abuse confidentiality rules would not normally apply to an emergency room).

It is also helpful to remember that the confidentiality rules only apply to patient-identifying records. 42 C.F.R. § 2.11. Medical records where patient names have been replaced with confidential patient identification numbers are not covered. As a result, depending on how your case proceeds and what information you truly need, you may be able to avoid the regulations by requesting records with the patient names redacted. One caution, however, is that the confidentiality rules apply if there is information in the records from which the patient's identity may be determined, directly or indirectly, "with reasonable accuracy and speed." 42 C.F.R. § 2.11 (definition of patient identifying). Relatedly, in the absence of consent or a court order, discussed below, the regulations prohibit a substance abuse treatment facility from even acknowledging that a particular individual is a patient. 42 C.F.R. § 2.13(c).

You should also be on the lookout for cases that involve a crime by a patient on the premises of the facility or a crime by a patient against program personnel. 42 C.F.R. § 2.12(c)(5). In those circumstances, the confidentiality rules do not apply. The exception is limited, however, to allow communication with law enforcement regarding the circumstances of the incident and the patient's whereabouts. Beyond that narrow category of information exchange, access is not permitted by § 2.12(c)(5).

III. How you can solve the problem

Having worked through the various categories when the confidentiality rules do not apply, you are presumably faced with a situation in which

you need to obtain access to confidential substance abuse medical records in order to further your investigation. When that happens, you need one of two things: compulsion or permission. 42 C.F.R. § 2.3(b)(1). Either alone is insufficient.

The most common forms of compulsion are search warrants and subpoenas. You do not necessarily need a grand jury subpoena—an IG subpoena will do. A HIPAA subpoena is equally effective.

In terms of permission, the regulations offer three options. The first is patient consent. But even in cases when you have a cooperative patient who is willing to provide a signed consent, do not make the mistake of relying on a generic consent form. Instead, under the regulations, you need to use a very specific consent form that includes details about the purpose of the disclosure, the documents to be disclosed, and the individuals who will have access. 42 C.F.R. § 2.31. In short, you must follow the sample consent form provided in the regulations. 42 C.F.R. § 2.31(b).

One twist is that the substance abuse consent form, 42 C.F.R. § 2.31 (b), was promulgated before HIPAA imposed additional requirements for medical consent forms, 45 C.F.R. § 164.508. The following are the elements of a substance abuse consent form:

- The name of the patient providing consent;
- The person or entity making the disclosure;
- A description of the information to be disclosed;
- The name of the person (or entity) that is authorized to receive the information;
- The purpose of the disclosure;
- The date the consent form is signed;
- The signature of the patient or guardian or authorized representative; and
- A notice that the consent may be revoked at any time except with respect to disclosures already made in reliance on the consent form.

42 C.F.R. § 2.31. The more recent HIPAA regulations include those same core elements, 45 C.F.R. § 164.508(c), but the following should be added:

- A notice regarding the prohibition, in certain circumstances, of conditioning treatment, payment, enrollment, or eligibility for benefits on the provision of a consent form;
- A notice regarding the potential for the information to be re-disclosed;
- The requirement that the authorization be written in plain language; and
- The requirement of providing the patient with a copy of the signed authorization.

45 C.F.R. § 164.508 (c)(2). In terms of the potential for re-disclosure of substance abuse records, the best language is found in 42 C.F.R. § 2.32, which generally prohibits re-disclosure in the absence of consent or a court order.

The second type of permission is a court order. Depending on the purpose for your record request, different regulatory sections apply. *Compare* 42 C.F.R. § 2.66 (criminal investigation or prosecution of a program); 42 C.F.R. § 2.65 (criminal investigation or prosecution of a patient); and 42 C.F.R. § 2.64 (noncriminal matters). However, regardless of the applicable section, you will need to establish, in general, the following:

- That you have a legally-recognized interest in the records;
- That there is no other way to obtain the information; and
- That the public interest in disclosure outweighs the confidentiality of the patient-physician relationship.

Your access will also be limited to the essential records, and access will only be allowed to those with a need to know. *See, e.g.*, 42 C.F.R. § 2.13 ("Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.") You must also agree to maintain the records in strict confidence, subject to

prohibitions on re-disclosure. 42 C.F.R. §§ 2.64, 2.65, 2.66.

The third type of permission is an audit and evaluation by a federal, state, or local agency responsible for oversight of Medicare or Medicaid. 42 C.F.R. § 2.53. In many ways, that authority is the most powerful and the most problematic. It is powerful because it allows virtually immediate access to the highly confidential records. It is problematic because it might require you to create a firewall between the information available to the investigating agency and the prosecutor.

A firewall might be necessary due to the subtleties in the audit and evaluation regulation, which provides as follows:

(c) Medicare or Medicaid audit and evaluation.

(1) For purposes of Medicare or Medicaid audit or evaluation under this section, audit or evaluation includes a civil or administrative investigation of the program by any Federal, State, or local agency responsible for oversight of the Medicare or Medicaid program and includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation.

(d) Limitations on disclosure and use. Except as provided in paragraph (c) of this section, patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute criminal or other activities, as authorized by a court order entered under § 2.66 of these regulations.

Id. § 2.53(c) & (d).

Before utilizing the audit and evaluation authority, one easily overlooked requirement is that the person conducting the audit and evaluation must agree in writing to maintain

patient confidentiality, destroy all patient identifying information upon completion of the audit or evaluation, and otherwise comply with the regulatory limitations on disclosure. 42 C.F.R. § 2.53 (a) & (b)(1). Obviously, the best course would be to provide that written assurance before embarking on an audit and evaluation so there is no doubt about the government's purpose and authority.

The audit and evaluation regulation raises several important considerations. At the outset, it is limited to investigations that are civil or administrative. Notably, criminal investigations are not included. Moreover, the regulatory authority "includes administrative enforcement, against the program by the agency, of any remedy authorized by law to be imposed as a result of the findings of the investigation." 42 C.F.R. § 2.53(c)(1). It is unclear, however, whether that also includes a United States Attorney's office (USAO) that uses civil enforcement based on information obtained from an administrative investigation. No court has ruled on the matter. Thus, even assuming the Department of Justice (Department) is an organization responsible for oversight of Medicare and Medicaid that has authority for a civil audit and evaluation investigation, it is uncertain whether that also allows for civil enforcement absent a court order.

Given those uncertainties, it is recommended that you allow the administrative agency (most likely the U.S. Department of Health and Human Services (HHS)) to perform any audit and evaluation without the disclosure of patient identifying information to the Department or USAO. Then, if the agency uncovers information that should be referred for criminal or civil enforcement, the agency could obtain (out of an abundance of caution) authorization by means of patient consent (42 C.F.R. § 2.31) or a court order (42 C.F.R. §§ 2.64, 2.65, 2.66).

Even if you obtain access to patient identifying information by meeting one or more of the requirements for compulsion and permission, there is one category of records that is subject to yet another level of protection: so-called confidential communications made by a patient to

a program staff member in the course of diagnosis, treatment, or referral. 42 C.F.R. § 2.63. In order to win access to those records, you must demonstrate that:

- Disclosure is necessary to protect against an existing threat to life or serious bodily injury;
- Disclosure is necessary in connection with investigation or prosecution of an extremely serious crime, such as homicide, rape, kidnaping, armed robbery, assault with a deadly weapon, or child abuse and neglect; or
- Disclosure is in connection with litigation or an administrative proceeding in which the patient offers testimony pertaining to the content of the confidential communications.

42 C.F.R. § 2.63. The list of extremely serious crimes is illustrative, not exclusive, and has been refined by the courts. *United States v. Hughes*, 95 F.Supp.2d 49, 58-59 (D. Mass. 2000) (on the narrow facts of the case, § 2.63 extremely serious crime requirement did not include possession of a firearm by a drug user); *In Re August 1993 Regular Grand Jury (Hospital Subpoena)*, 854 F.Supp. 1380, 1385 (S.D. Ind. 1994) (government declined to assert doubtful argument that fraudulent billing is an extremely serious crime under § 2.63).

IV. What are the strategic considerations?

Before you embark on a drug case or health care fraud investigation that involves confidential substance abuse records, you should stop and think about several strategic considerations. First, you should consider whether your investigation will be compromised by a record request that triggers notice to the affected patients. If your investigation is civil, the regulations require immediate notice to affected patients. 42 C.F.R. § 2.64. If your investigation is criminal, however, the regulations allow for an ex parte order to avoid compromising the investigation. 42 C.F.R. § 2.66(b). In a criminal case, the First Circuit has upheld a district court's decision to allow for 180 days delayed notification to patients, even though the confidentiality regulations provide for notice

"upon implementation" of any court order authorizing disclosure. *Shinderman*, 515 F.3d at 11-13.

Second, extreme care is required if patients are likely to be prosecuted. The entire purpose of the regulations is to protect patient confidentiality so as not to deter substance abuse patients from seeking treatment. Accordingly, if you need court-ordered access to records in order to prosecute patients, the regulations require the following:

- The case must involve an extremely serious crime;
- The records must be reasonably likely to provide information of "substantial value";
- The other ways of obtaining the information would not be effective; and
- The potential injury to the patient and patient-physician relationship is outweighed by the public interest in disclosure.

42 C.F.R. § 2.65(d). Since the § 2.65 definition of an extremely serious crime is the same as that for § 2.63, referenced above, it pays to check the case law under both sections. *Compare United States v. Corona*, 849 F.2d 562 (11th Cir. 1988) (under § 2.65, purchase of firearms by a substance abuse addict was "extremely serious") with *United States v. Hughes*, 95 F.Supp.2d 49, 58-59 (D. Mass. 2000) (under § 2.63, false statement by a drug user in possession of a firearm and while purchasing a firearm was not "extremely serious").

Third, before you attempt an undercover investigation in a substance abuse treatment facility, you must obtain a court order. 42 C.F.R. § 2.67. For court authorization of an undercover operation, you need to demonstrate that:

- There is reason to believe an employee is engaged in criminal activity;
- Other ways of obtaining the evidence would not be effective; and
- The public interest in disclosure outweighs risk of harm to the patient and/or the patient-physician relationship.

42 C.F.R. § 2.67(c). You will also be required to provide notice of the undercover operation to the clinic's program director unless your application asserts a belief that the program director is involved in the criminal activities to be investigated or that the program director will disclose the existence of the undercover operation. 42 C.F.R. § 2.67(b).

Finally, if a court authorizes you to seize a large number of confidential substance abuse records, you should consider the interplay with other ongoing investigations in your office. For example, after seizing the records, you may be surprised to learn that several patients are either witnesses or defendants in other cases prosecuted by your office. In that situation, your obligation to maintain the confidentiality of the substance abuse records might conflict with your *Brady* and *Giglio* disclosure obligations in those other cases. At that point, the only solution is patient consent or a court order. In such circumstances, your office should also consider the use of a taint team to monitor any overlap between the patient records you seized and the witnesses and defendants in other cases prosecuted by your office who are subject to *Brady* and *Giglio* disclosure requirements.

V. Case study

The following example is based on a Maine case in which the USAO successfully prosecuted the following parallel proceeding:

- Criminal charges against a doctor for forging controlled substance prescriptions, falsifying records, and engaging in health care fraud; and
- Civil claims against the doctor's methadone clinic for improperly allowing certain patients to "take home" methadone (which occasionally resulted in diversion and overdose death), failing to maintain proper DEA records of methadone supply and distribution, and Medicaid billing fraud.

Each step illustrates the applicable rules from 42 C.F.R. Part II.

A. Step 1: The investigation

The investigation began in response to an unusual spike in overdose deaths in southern Maine. Typically, the cause of death was a multi-drug overdose but a common thread was the presence of methadone, the source of which, in some instances, could be traced to a local methadone clinic.

In response to the public health crisis, the HHS, Office of Inspector General (OIG), commenced an administrative investigation. Compliance with 42 C.F.R. Part II was required because the clinic's confidential records unquestionably involved drug abuse treatment. 42 C.F.R. § 2.11. To gain immediate access to the records, OIG commenced an audit and evaluation and provided contemporaneous written assurances that it would maintain patient confidentiality and comply with the limitations on redisclosure. 42 C.F.R. § 2.53 (a) & (b). To avoid any risk under the subtle audit and evaluation regulations, patient-identifying information was not provided to the USAO at this stage in the investigation.

B. Step 2: The discovery of criminal violations

As the administrative investigation proceeded, OIG received information from a patient that a doctor at the methadone clinic had issued prescriptions for controlled substances by using another doctor's prescription pad and DEA registration. OIG's review of clinic records confirmed the allegation. Accordingly, OIG had reason to believe the doctor had committed a crime in violation of 21 U.S.C. § 843.

The USAO requested a court order that would authorize OIG to share with the criminal prosecutors the confidential fruits of the audit and evaluation. The request was made pursuant to 42 C.F.R. § 2.66, which allowed for an ex parte order so as not to compromise the ongoing investigation. The district court granted the request and authorized delayed notification to the affected patients.

Notably, access was not requested for the civil side of the USAO. One reason was that the

regulations authorizing disclosure for a noncriminal purpose do not include a provision for an ex parte order. 42 C.F.R. § 2.64. Accordingly, if the USAO had requested access for civil enforcement, the court would have required advanced notice to the clinic, which would have compromised the ongoing investigation. Moreover, at this point in the case, access for civil enforcement was not necessary. Indeed, given the general nature of civil health care cases, it was entirely possible that affirmative civil enforcement could have been accomplished using confidential patient-identification numbers, without access to patient-identifying information. If access had been necessary, the Civil Division could have requested its own court order or it could have asserted its authority to access the confidential records pursuant to the audit and evaluation regulations.

C. Step 3: The search warrant

Upon review and further investigation, OIG and the criminal division of the USAO decided to apply for a search warrant to obtain the methadone clinic's patient records and a mirror image of the clinic's computer. In support of the search warrant application, the USAO filed a motion that requested permission to seize confidential substance abuse medical records. Since criminal prosecution was the purpose, an ex parte motion was filed pursuant to 42 C.F.R. § 2.66. Again, access was not requested for the civil side of the USAO. The district court granted the application for a search warrant and the supporting motion for access to the confidential records. After execution of the search warrant, the USAO provided notice, pursuant to 42 C.F.R. § 2.66 (b), to all patients whose records were seized.

D. Step 4: Access for the civil litigation

The execution of the search warrant and the ongoing investigation revealed that the methadone clinic was subject to civil prosecution for:

- Improperly dispensing take-home methadone to patients who diverted the drugs, which sometimes resulted in death;
- Failing to maintain proper DEA record keeping for methadone dispensing and supplies; and
- Overbilling Medicaid for unnecessary and substandard services.

At that point, it became necessary for the civil side of the USAO to access the confidential patient-identifying information, at a minimum, in order to provide discovery in the ongoing parallel civil case against the methadone clinic. Moreover, after the execution of the search warrant, there was no fear of compromising an ongoing criminal investigation. Accordingly, as the parallel civil case proceeded, the Civil Division of the USAO filed a motion, which the court granted, requesting a Protective Order that allowed access to the confidential records by all parties in the ongoing civil case, subject to strict confidentiality requirements and in accordance with 42 C.F.R. § 2.64.

E. Step 5: Trial and civil settlement

For the criminal trial against the doctor, the USAO obtained written consent, pursuant to 42 C.F.R. § 2.31, for most of the patients who testified. The 1-week jury trial resulted in a 58-count conviction and a sentence of 6 months in prison and 6 months of home confinement. *United States v. Shinderman*, 474 F. Supp.2d 180 (D. Me. 2007).

A civil trial was not necessary because the methadone clinic settled the claims (by payment of \$1 million) soon after the government won a novel summary judgment motion that established liability for dozens of Title 21 illegal drug distribution penalties based on the clinic's violation of Title 42 take-home methadone regulations. *United States v. CAP Quality Care, Inc.*, 486 F. Supp.2d 47 (D. Me. 2007).

VI. Conclusion

As is often the case in the federal prosecution of drug and health care cases, access to the underlying medical records can make the difference between success and failure. Increasingly, access to that information will be governed by the unique substance abuse confidentiality rules of 42 C.F.R. Part II. By following the subtle rules that protect those double secret records, the government can increase the likelihood of success, protect patient confidentiality, and avoid the types of challenges that might otherwise derail the prosecution. ❖

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Approval Is Required For Non-Health Oversight Derivative Use of Medical Records

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This article serves as a reminder of the general rule that personal medical information disclosed to the Department of Justice (Department) in the course of health oversight investigations, litigation, or proceedings cannot be used against an individual patient in an unrelated, non-health care oversight investigation, civil or criminal litigation, or administrative proceeding (derivative use). However, if a derivative use is necessary notwithstanding the general rule, one of two procedures must be followed to obtain permission for the desired non-health oversight use. The choice of procedure to follow is dictated by the manner in which the Department obtained the personal medical information:

- By health care fraud administrative subpoena issued pursuant to 18 U.S.C. § 3486 (2003) (§ 3486 subpoena) or by another means, such as:
- A voluntary disclosure;
- A grand jury subpoena;
- An Inspector General subpoena;
- A civil subpoena; or
- During the execution of a search warrant.

As a further precautionary note and as discussed below, be aware that the types of cases to which the general prohibition against derivative use applies may include a broader universe of matters than is apparent at first blush. The cases may reach certain types of Title 21 cases, for

example, involving the fraudulent dispensation or diversion of controlled pharmaceuticals.

The Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (HIPAA), enacted robust new health care antifraud statutes. These statutes included new administrative subpoena authority, which was constrained by a general prohibition on the government's derivative use of individual health information produced in response to the new § 3486 subpoenas, for any purpose unrelated to the payment for or receipt of health care or a fraudulent claim related to health care. Section 3486(e) requires that an application for a derivative use be made to an appropriate court, which is required to make a finding of good cause before it can authorize a derivative use otherwise prohibited.

The forgoing restrictions apply only to protect the discrete universe of personal medical records produced to the government in compliance with a § 3486 subpoena. Presidential Executive Order 13,181 was issued on December 20, 2000 (Exec. Order No. 13,181, 65 Fed. Reg. 81,321 (Dec. 26, 2000)). Executive Order 13,181 was issued to protect the balance of personal health information obtained by the government during a health oversight matter by means other than a § 3486 subpoena, including grand jury subpoenas, voluntary disclosure, civil subpoenas (in qui tam matters), Inspector General subpoenas, or pursuant to a search warrant.

Executive Order 13,181 generally prohibits the use of this broader universe of nonsection 3486 subpoena health oversight personal health information against an individual, for a non-health care oversight derivative use. Analogous to the judicial procedure provided in § 3486(e), Executive Order 13,181 provides a procedure by

which permission for an otherwise prohibited derivative use can be sought from the Deputy Attorney General (DAG) (or the General Counsel of the Department of Defense, if the protected health information involves members of the Armed Services). The DAG "shall permit such use upon concluding that the balance of relevant factors weighs clearly in favor of its use. That is, the DAG shall permit disclosure if the public interest and the need for disclosure clearly outweigh the potential of injury to the patient, to the physician-patient relationship, and to the treatment services." Exec. Order No. 13,181 § 3(b). The DAG "in determining the extent to which the information should be used, shall impose appropriate safeguards against unauthorized use." Exec. Order 13,181 § 3(c).

In conjunction with the release of Executive Order 13,181, the Director of the Executive Office for United States Attorneys circulated an interim procedure for applying for permission to use derivative information under the order. The memorandum provided that:

Until a permanent procedure is established and until further guidance is circulated, you should direct requests for derivative use of protected health information obtained during a health oversight investigation subject to the Executive Order to . . . the Deputy Chief [currently Kirk Ogrosky], or Ian C. Smith DeWaal, Senior Counsel, Criminal Division, Fraud Section, who will forward the requests to the appropriate individuals. You may reach [Kirk Ogrosky] or Ian DeWaal at (202) 514-0640.

Memorandum from Mark Calloway, Director, Executive Office for United States Attorneys on Medical Records Privacy Regulation and Executive Order Restricting the Derivative Use of Protected Health Information - New Procedures (May 18, 2001). The Memorandum follows this article. The Fraud Section continues to be the first point of contact for requests for authorization for the derivative use of protected health information produced by means other than a § 3486 subpoena.

Two final cautions:

- First, Executive Order 13,181 includes a broad definition of what is a covered health oversight activity. The Order provides that "health oversight activities" include the oversight activities promulgated by the Secretary of Health and Human Services pursuant to HIPAA. The Secretary has determined that health oversight includes "oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative or criminal proceedings or actions; or other activities necessary for appropriate oversight of: (i) The health care system; (ii) Government benefit programs for which health information is relevant to beneficiary eligibility; (iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or (iv) Entities subject to civil rights laws for which health information is necessary for determining compliance."

45 C.F.R. §164.512 (d).

- Second, there are mandatory separate procedures for derivative use of substance abuse patient medical records provided for in 42 C.F.R. Part 2.❖

ABOUT THE AUTHOR

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Executive Office for United
States Attorneys
Office of the Director

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Washington, D.C. 20530

MEMORANDUM - Sent via Electronic Mail

DATE: May 18, 2001

TO: ALL UNITED STATES ATTORNEYS
ALL FIRST ASSISTANT UNITED STATES ATTORNEYS
ALL CRIMINAL CHIEFS
ALL CIVIL CHIEFS

FROM: Mark T. Calloway
Director

SUBJECT: Medical Records Privacy Regulation and
Executive Order Restricting the Derivative
Use of Protected Health Information - New Procedures

ACTION REQUIRED: Distribute to all Assistant United States Attorneys

CONTACT PERSON: Luis M. Matos
Health Care Fraud Coordinator
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On April 12, 2001, President Bush announced that the administration would implement a comprehensive medical records privacy regulation that was first issued by the Department of Health and Human Services ("HHS") late last year, but had been under review. When the regulation was first announced on December 20, 2000, former President Clinton also issued Executive Order No. 13181 that restricts the derivative use of protected health information by all federal agencies including federal law enforcement personnel. This memorandum provides information about both the medical records privacy regulation and the Executive Order.

The full text of the medical records privacy regulation issued by HHS can be downloaded from HHS's website at <http://www.aspe.hhs.gov/admnsimp>"<http://www.aspe.hhs.gov/admnsimp>.

A fact sheet outlining the general parameters of the regulation may also be found at <http://www.hhs.gov/news/press/2000pres/00fsprivacy>. In general, the regulation addresses the circumstances under which "covered entities," such as health plans, health care clearinghouses, and health care providers who conduct certain financial and administrative transactions, may release patients' medical information. The regulation does not directly govern the conduct of law enforcement personnel. However, the regulation is relevant to law enforcement, health care fraud, and civil litigation activities because the regulation, in part, addresses the circumstances under which "covered entities" may disclose information in response to government inquiries or in response to legal process.

The effective date of the final rule is April 14, 2001. "Covered entities" must comply with the regulation within two years of its effective date, or by April 14, 2003. A corporation may comply with the regulation prior to April 14, 2003, however, the "regulation itself will neither compel disclosure nor provide a basis to refuse disclosure" prior to the compliance deadline of April 14, 2003. 65 Fed. Reg. 82944. In other words, the regulation should not provide the basis for a party's reluctance to comply with an inquiry from law enforcement until April 14, 2003. Nonetheless, the regulation will eventually affect the manner in which covered entities will comply with law enforcement requests. Accordingly, the Department is in the process of reviewing the final rule and will send additional guidance once it is developed.

The Executive Order

The Executive Order signed by former President Clinton on December 20, 2000, restricts the derivative use of protected health information by all federal agencies, including federal law enforcement personnel. The Executive Order is effective immediately. A copy of the Executive Order is attached.

The Executive Order directs that whenever protected health information is obtained by a federal law enforcement agency for the purpose of a health oversight function, that health information cannot be used against a patient for a civil, administrative, or criminal investigation of a non-health oversight matter without prior approval by the Deputy Attorney General ("DAG"). The DAG may not approve the requested derivative use ". . . unless the public interest and the need for disclosure clearly outweigh the potential for injury to the patient, to the physician-patient relationship, and to the treatment services."

Therefore, the Executive Order limits the use of information obtained from medical records during an investigation of a program for which health status is a condition of eligibility, such as a health care fraud investigation, a Food, Drug, and Cosmetics Act investigation, or a civil rights investigation. In the context of such investigations, if medical records are reviewed and they appear to contain evidence of a violation other than that being investigated, then that information cannot be used to pursue such a derivative investigation absent authorization from the DAG. For instance, if a medical record obtained during an investigation of fraudulent Medicare billings contains a statement by a patient that he has embezzled money from his employer, that statement may not be used to pursue a case against the patient without first obtaining approval from the DAG.

The Executive Order does not apply to the use of the protected health information in subsequent "health oversight activities." [FN1] It also does not apply to the special procedures for protected health information obtained pursuant to health care fraud administrative subpoenas issued pursuant to 18 U.S.C. §167; 3486, and does not supercede any duties imposed by law.

Until a permanent procedure is established and until further guidance is circulated, you should direct requests for derivative use of protected health information obtained during a health oversight investigation subject to the Executive Order to either Karen Morrissette, Deputy Chief, or Ian C. Smith DeWaal, Senior Counsel, Criminal Division, Fraud Section, who will forward the requests to the appropriate individuals. You may reach Karen Morrissette or Ian DeWaal at (202) 514-0640.

If you have any questions, please contact Lou Matos at (202)353-8507.

Attachment

cc: All United States Attorneys' Secretaries

FN 1. "Health oversight activities" are defined in the Executive Order to "include the oversight activities enumerated in the regulations concerning the confidentiality of individually identifiable health information promulgated by the Secretary of Health and Human Services pursuant to the 'Health Insurance Portability and Accountability Act of 1996,' [HIPAA] as amended." According to the regulation, individually identifiable health information includes health information collected from an individual which is created or received by a health care provider, and which relates to the past, present, or future physical or mental health condition of an individual, the provision of health care to an individual, or payment for the provision of health care, and which identifies or may reasonably be expected to identify an individual. See 45 C.F.R. § 164.164.501. Health oversight agencies include agencies which oversee government benefit programs for which health status is a condition of eligibility or which enforce the civil rights laws. Id. "Health oversight activities" are further enumerated in 45 C.F.R. § 164.512(d).

Freezing Assets in Health Care Fraud Cases

Ana Maria Martinez
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I. Introduction

Health care fraud against the Medicare and Medicaid programs causes billions of dollars in losses each year. Criminal and civil enforcement results in significant recoveries through criminal restitution, forfeitures, and civil settlements and judgments. In many cases, however, the perpetrators move the money as quickly as it is deposited. This article focuses on the fraud injunction statute, 18 U.S.C. § 1345 (2002), which provides for the freezing of assets before it is too late.

One of the most effective uses of the fraud injunction statute has been to freeze bank accounts in cases involving sham health care companies. These companies bill Medicare millions of dollars in just a few months for services or drugs that are not medically necessary or not provided at all. Typical cases have involved billings for durable medical equipment (DME) such as wheelchairs, mattresses, braces, oxygen concentrators, and diabetic supplies. Another typical scheme involves billing millions for Human Immunodeficiency Virus infusion treatments. More recently, § 1345 has also been used to freeze bank accounts in cases involving fraud against health maintenance organizations (HMOs) funded by Medicare.

A case filed under § 1345 is a unique type of civil proceeding. It begins with a civil complaint but requires evidence of a crime listed in § 1345. While this article focuses on health care fraud, the fraud injunction statute extends to other frauds such as mail fraud, wire fraud, and bank fraud. If a criminal indictment is filed, discovery in the § 1345 case changes from the civil rules of procedure to the criminal rules.

In some cases the government may seek damages under the civil False Claims Act, 31 U.S.C. § 3729-3731 (the FCA), as well as injunctive relief under 18 U.S.C. § 1345. In such cases, courts will generally grant a motion for a temporary restraining order (TRO) and a preliminary injunction based on an adequate showing of a crime listed in § 1345. However, a violation of the FCA does not provide a basis for injunctive relief under 18 U.S.C. § 1345. *United States v. Sriram*, 147 F. Supp. 2d 914, 946 (N.D. Ill. 2001). There also is no provision under § 1345 to freeze the treble damages provided for under the FCA. *Id.* at 947. Still, the Fourth Circuit has held that a court's general equitable power and Federal Rule of Civil Procedure 64 authorize injunctive relief to serve the public interest and maintain the status quo where both damages and equitable relief are sought. *See United States ex rel. Rahman v. Oncology Assocs.*, 198 F.3d 489, 496-501 (4th Cir. 1999).

This article provides an overview of § 1345 proceedings. First, the article identifies some practical issues with respect to parallel proceedings. Next, the article discusses the requirements for filing a § 1345 case and obtaining a TRO and a preliminary injunction. The article then addresses motions, discovery, trials, and judgments. The article also outlines the steps for obtaining relief in cases where defendants disappear. The article concludes that the continued use of the fraud injunction statute to freeze assets is critical to the fight against health care fraud.

II. Parallel proceedings

Parallel proceedings refer to other legal proceedings that involve the same facts. For example, a criminal investigation may be underway when a civil Assistant United States Attorney (AUSA) is asked to seek a TRO under

18 U.S.C. § 1345. Civil and criminal AUSAs need to coordinate with each other, and they also need to be sure the coordination is proper and not subject to claims of abuse.

The first practical issue is risk of flight. If a parallel criminal investigation is not sufficiently advanced for an arrest to be made simultaneously with the freezing of assets, the flight risk of the defendant should be considered before filing the § 1345 case. A TRO may be requested ex parte but the court will order that notice be given quickly after the assets are frozen.

The civil and criminal AUSAs should also coordinate with asset forfeiture AUSAs. In some cases, assets can be seized or restrained through provisions in forfeiture statutes instead of using the fraud injunction statute. However, in such cases, the filing of a civil forfeiture case or an indictment with a criminal forfeiture allegation must soon follow in accordance with statutory time frames.

Another consideration is the appropriate sharing of evidence. Some of the evidence gathered in a criminal investigation may be considered grand jury material. In appropriate cases, an order may be obtained under Federal Rule of Criminal Procedure 6(e) for certain evidence to be used for the § 1345 proceeding.

Each type of proceeding must be conducted in good faith and must be used for its proper purpose. The processes of one type of proceeding may not be improperly used for purposes of the parallel proceeding. In some cases, defendants have claimed that the civil proceedings were inappropriately used to gather evidence for the criminal investigation. In such cases, courts scrutinize the conduct of the government. *See United States v. Stringer*, 535 F.3d 929 (9th Cir. 2008) (reversing dismissal of indictment where defendants were advised of their Fifth Amendment rights and the Securities and Exchange Commission (SEC) made no misrepresentations); *United States v. Posada Carriles*, 541 F.3d 344, 356-61 (5th Cir. 2008) (reversing dismissal of indictment where defendant had applied for naturalization and was advised of his Fifth Amendment rights);

United States v. Scrushy, 366 F. Supp. 2d 1134, 1138-40 (N.D. Ala. 2005) (suppressing statements made in prior SEC deposition because of prosecutor's input regarding location and content of deposition).

In some cases, the parties in a civil proceeding will seek a stay pending the completion of a parallel criminal proceeding. *See, e.g., Ashworth v. Albers Med., Inc.*, 229 F.R.D. 527, 532 (S.D. W. Va. 2005) (granting pre-indictment stay); *Baranski v. Fifteen Unknown Agents of ATF*, 195 F. Supp. 2d 862, 870-71 (W.D. Ky. 2002) (same). However, stays are not always granted. *See, e.g., Microfin., Inc. v. Premier Holidays Int'l, Inc.*, 385 F.3d 72, 79 (1st Cir. 2004); *Horn v. District of Columbia*, 210 F.R.D. 13, 16 (D.D.C. 2002).

III. TRO application and preliminary injunction hearing

A. Documents that must be filed

A proceeding under 18 U.S.C. § 1345 is initiated by filing a civil complaint laying out the:

- Jurisdiction
- Parties
- Fraud
- Dissipation of assets
- Request for relief

At the same time, a motion for a TRO and a preliminary injunction is filed along with:

- A memorandum of law;
- An affidavit with evidence to support the TRO request;
- A declaration stating whether prior notice was provided or whether notice was not provided because it would risk further dissipation of assets; and
- A proposed TRO.

B. Elements that must be established and relief that is available

Title 18 U.S.C. § 1345 (2002) states what must be established to obtain relief and the relief available.

§ 1345. Injunctions against fraud

(a)(1) If a person is –

(A) violating or about to violate this chapter or section 287, 371 (insofar as such violation involves a conspiracy to defraud the United States or any agency thereof), or 1001 of this title;

(B) committing or about to commit a banking law violation (as defined in section 3322(d) of this title); or

(C) committing or about to commit a Federal health care offense;

the Attorney General may commence a civil action in any federal court to enjoin such violation.

(2) If a person is alienating or disposing of property, or intends to alienate or dispose of property, obtained as a result of a banking law violation (as defined in section 3322(d) of this title) or a Federal health care offense or property which is traceable to such violation, the Attorney General may commence a civil action in any Federal court–

(A) to enjoin such alienation or disposition of property; or

(B) for a restraining order to –

(I) prohibit any person from withdrawing, transferring, removing, dissipating, or disposing of any such property or property of equivalent value; and

(ii) appoint a temporary receiver to administer such restraining order.

(3) A permanent or temporary injunction or restraining order shall be granted without bond.

(b) The Court shall proceed as soon as practicable to the hearing and determination

of such an action, and may at any time before final determination, enter such a restraining order or prohibition, or take such other action, as is warranted to prevent a continuing and substantial injury to the United States or to any person or class of persons for whose protection the action is brought. A proceeding under this section is governed by the Federal Rules of Civil Procedure, except that, if an indictment has been returned against the respondent, discovery is governed by the Federal Rules of Criminal Procedure.

In summary, if the United States establishes an ongoing violation of a crime listed in § 1345(a)(1), or that such a violation is about to be committed, the statute authorizes the court to issue an injunction to stop ongoing or future violations. In either case, if the United States establishes that fraud proceeds have been dissipated or are likely to be dissipated, § 1345(a)(2) authorizes the court to enter a restraining order to stop the dissipation and prohibit the transfer or disposition of "any such property or property of equivalent value."

Section 1345 further provides that the court may appoint a receiver or grant other equitable relief. The court may "take such other action, as is warranted to prevent a continuing and substantial injury to the United States or to any person or class of persons for whose protection the action is brought." 18 U.S.C. § 1345(b).

A fraud injunction sought by the United States is different than the typical motions for TROs and preliminary injunctions in civil cases between private parties. The traditional test for the issuance of a temporary restraining order does not apply where the government is seeking an injunction pursuant to a federal statute that was enacted to protect the public interest and that authorizes injunctive relief. *United States v. Sriram*, 147 F. Supp. 2d 914, 935-37 (N.D. Ill. 2001); *United States v. Medina*, 718 F. Supp. 928, 930 (S.D. Fla. 1989).

Courts have held that the government is not required to make a traditional showing of irreparable harm when seeking a § 1345 injunction. *See United States v. Hoffman*, 560 F.

Supp. 2d 772, 776 (D. Minn. 2008) (threat of substantial injury may substitute for irreparable harm); *United States v. Williams*, 476 F. Supp. 2d 1368, 1377 (M.D. Fla. 2007) (irreparable harm may be presumed); *United States v. Livdahl*, 356 F. Supp. 2d 1289, 1290-91 (S.D. Fla. 2005) (no irreparable harm showing required). The government also is not required to show the inadequacy of other remedies at law. *See Livdahl*, 356 F. Supp. 2d at 1291; *United States v. Fang*, 937 F. Supp. 1186, 1199 (D. Md. 1996). Furthermore, courts generally presume that the balance of hardships tips in favor of the government. *See Williams*, 476 F. Supp. 2d at 1377; *Livdahl*, 356 F. Supp. 2d at 1291; *Sriram*, 147 F. Supp. 2d at 935-37.

There is a split in the circuits over whether the government must trace proceeds of the fraud to the specific bank accounts or properties that the government seeks to restrain. The Eleventh Circuit has held that, as explicitly stated in 18 U.S.C. § 1345, the district court may freeze assets of "equivalent value" to the fraud proceeds, without regard to whether the specific assets are traceable to the fraud. *United States v. DBB, Inc.*, 180 F.3d 1277, 1283-84 (11th Cir. 1999). However, in a case where the majority of the defendant's income was not from Medicare, the Sixth Circuit stated that the government was required to link the fraud to the assets it was seeking to restrain. *See United States v. Brown*, 988 F.2d 658, 664 (6th Cir. 1993). Still, some courts have ruled that once the government has established a criminal violation, the burden shifts to the defendant to show that the assets at issue are not the proceeds of the fraud. *See Fang*, 937 F. Supp. at 1198-99; *United States v. William Savran & Assoc.*, 755 F. Supp. 1165, 1183 (E.D.N.Y. 1991); *see also U.S. v. Liner*, 97 Fed. Appx. 74, 75 (8th Cir. 2004) (scope of injunction affirmed where defendant refused to offer evidence as to the source of the frozen assets).

C. Burden of proof

There are also differences among the courts in the various federal judicial circuits with respect to the level of proof required to obtain the TRO and preliminary injunction under § 1345. Some courts

have used a probable cause standard. *See Livdahl*, 356 F. Supp. 2d at 1293-94; *Savran*, 755 F. Supp. at 1177. Other courts have used a preponderance of the evidence standard. *See Brown*, 988 F.2d at 663-64; *Hoffman*, 560 F. Supp. 2d at 777; *Williams*, 476 F. Supp. 2d at 1374; *Sriram*, 147 F. Supp. 2d at 938.

Some courts appear to combine standards of proof. *See Fang*, 937 F. Supp. at 1198 (reasonable probability); *United States v. Weingold*, 844 F. Supp. 1560, 1573 (D.N.J. 1994) (preponderance of evidence that probable cause exists). Other courts decline to decide which is the appropriate level of proof because the government's evidence satisfies the higher civil standard of preponderance of the evidence. *See United States v. Legro*, 2008 WL 2605104, *3 (5th Cir. July 2, 2008).

D. Evidentiary considerations

Hearsay is permissible in the affidavit to support the motion for the TRO and at the preliminary injunction hearing. *Levi Strauss & Co. v. Sunrise Intern. Trading, Inc.*, 51 F.3d 982, 985 (11th Cir. 1995). Courts generally caution, however, that while hearsay is admissible, less weight may be given to hearsay than to testimony or other exhibits that meet the requirements of the Federal Rules of Evidence.

In cases where the preliminary injunction is contested, the United States generally calls the defendants to the stand. The defendant must decide whether to invoke the Fifth Amendment to fully guard against possible use of the testimony in a criminal case that may follow. Because § 1345 is a civil proceeding, an adverse inference may be drawn from the invocation of the Fifth Amendment. *Baxter v. Palmigiano*, 425 U.S. 308, 318-19 (1976).

IV. Defense motions to release assets

In addition to contesting the preliminary injunction or its scope, defendants may move for the release of assets for specific purposes such as attorney's fees or living expenses. Court rulings on such motions vary. Factors that courts have considered include:

- The strength of the government's evidence of fraud and the extent of the losses caused by the fraud;
- Whether there is evidence that the defendant had some legitimate source of income;
- Whether courts in that circuit require evidence linking each asset to the fraud or allow the § 1345 injunction to include "equivalent assets;"
- The balance of hardships;
- Whether the requests for attorney's fees or living expenses are reasonable and substantiated; and
- Whether the attorney's fees are for a civil case or a criminal case.

In cases where it is shown that the funds are proceeds of a crime, it is well settled that such funds cannot be used for attorney's fees. *See Caplin v. United States*, 491 U.S. 617, 626 (1989); *United States v. Monsanto*, 491 U.S. 600, 614 (1989). As explained by the Supreme Court:

A robbery suspect, for example, has no Sixth Amendment right to use funds he has stolen from a bank to retain an attorney to defend him if he is apprehended. The money, [al]though in his possession, is not rightfully his. . . . No lawyer, in any case, . . . has the right to . . . accept stolen property . . . in payment of a fee

Caplin, 491 U.S. at 626 (quotation omitted). *See also S.E.C. v. Quinn*, 997 F.2d 287, 289 (7th Cir. 1993) (swindler cannot use victims' assets to hire counsel to help him retain the gleanings of crime).

Courts have denied requests for attorney's fees, recognizing the harm that would be caused to the victims if funds were released. *See S.E.C. v. Current Fin. Serv.*, 62 F. Supp. 2d 66, 69 (D.D.C. 1999); *S.E.C. v. Bremont*, 954 F. Supp. 726, 733 (S.D.N.Y. 1997); *see also United States v. Grasso*, 500 F. Supp. 2d 511, 514 (E.D. Pa. 2007) (addressing requests for funds frozen under § 1345 only after restitution had been paid to victims). Courts will look at the facts of each case, though, and in appropriate cases may release some

funds for fees or living expenses. *See, e.g., United States v. Liner*, 97 Fed. Appx. 74, 75 (8th Cir. 2004) (affirming scope of injunction noting district court had allowed some funds for living expenses); *United States v. Payment Processing Center, LLC*, 439 F. Supp. 2d 435, 441 (E.D. Pa. 2006) (holding that some funds frozen under § 1345 may be released for attorney's fees if defendants submit financial disclosures justifying the use of restrained assets); *S.E.C. v. Duclaud Gonzalez de Castilla*, 170 F. Supp. 2d 427, 430 (S.D.N.Y. 2001) (releasing some funds for attorney's fees where "inference upon which the freeze was granted may not be supported").

V. Discovery

If the § 1345 case is not stayed, discovery will proceed under the civil rules unless an indictment is filed. After that, discovery in the § 1345 proceeding will be governed by the criminal rules.

In civil discovery, defendants sometimes attempt to make a blanket assertion of the Fifth Amendment; however, a civil litigant is required to claim the privilege with respect to each specific interrogatory or deposition question. *See Anglada v. Sprague*, 822 F.2d 1035, 1037 (11th Cir. 1987). This is required so that the court can properly evaluate the claim of privilege. *See id.* The United States also may ask the court to make a permissible adverse inference if the privilege is invoked with respect to specific questions. *Baxter v. Palmigiano*, 425 U.S. 308, 318-19 (1976); *Sriram*, 147 F. Supp. 2d at 930; *Bremont*, 954 F. Supp. at 732-33. Sometimes a defendant may have waived the Fifth Amendment as to a subject matter. *See, e.g., Nutramax Lab. v. Twin Lab.*, 32 F. Supp. 2d 331, 336-37 (D. Md. 1999) (civil litigant who voluntarily testified by affidavit waived Fifth Amendment privilege); *United States v. Gwinn*, 2003 WL 23357667 *6 (M.D. Fla. Aug. 15, 2003) ("Where a witness provides statements as to his finances in papers submitted to the court, he is deemed to have waived his Fifth Amendment privilege on the same subject matter.")

In some § 1345 proceedings, the defendants are corporations, which do not have Fifth

Amendment rights. *Braswell v. United States*, 487 U.S. 99, 108-09 (1988). Moreover, corporations cannot use the Fifth Amendment right of the owners to avoid discovery. *Id.* at 115-18. *Braswell* was the sole shareholder of his corporation. The Supreme Court held that a corporate custodian must produce corporate records even if "his act of production will be personally incriminating." *Id.* at 117. "Any claim of Fifth Amendment privilege asserted by the agent would be tantamount to a claim of privilege by the corporation—which of course possesses no such privilege." *Id.* at 110.

Thus, for discovery purposes, corporate defendants must designate an individual to appear at depositions and to respond to discovery. *Id.* at 116-18; *Nutramax*, 32 F. Supp. 2d at 337-38 (corporation must designate a person with knowledge for Rule 30(b)(6) deposition and to answer interrogatories). Corporate defendants may not avoid discovery by designating someone who will invoke the Fifth Amendment. If necessary, corporations must designate a person who will not invoke the Fifth Amendment as to the areas for which the owner invokes it. Corporations must also provide the designated person with the information or records necessary to adequately respond for the corporation. *See Braswell*, 487 U.S. at 116-18; *Nutramax*, 32 F. Supp. 2d at 337-38.

VI. Summary judgment

Summary judgment is granted where the pleadings, depositions, and affidavits show that there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A summary judgment motion should be accompanied by declarations, depositions, and exhibits that establish the elements of § 1345. In Medicare fraud cases this would include:

- Evidence of the claims submitted to Medicare, with redactions to protect privacy;
- Evidence that the claims were false or fraudulent;
- Evidence of payment; and

- Evidence of the dissipation of the fraud proceeds.

In cases involving sham companies, the evidence of fraud may be undisputed. There may be bank records that show there were no purchases of medical supplies or drugs. There may also be evidence that there was no real medical office or medical files. In some cases, doctors may provide declarations or deposition testimony indicating that they did not treat or prescribe for the patients, even though the defendants submitted claims to Medicare alleging those doctors had done so.

In cases where the defendants have invoked the Fifth Amendment, there may be no evidence to rebut a well-supported summary judgment motion. There also may be no dispute in cases where the defendant has pled guilty to related criminal charges. *See United States v. Sriram*, 2008 WL 516306 *5 (N.D. Ill. Feb. 26, 2008) (granting partial summary judgment on FCA counts). Thus, a summary judgment motion may well resolve the case without a trial.

VII. Trial

Most § 1345 proceedings do not proceed to trial. If there is a trial, it will be a bench trial, and the parties may agree to rely on some of the evidence that was presented at the preliminary injunction hearing. The burden of proof will be the civil burden of proof, a preponderance of the evidence.

VIII. Final judgments

Under § 1345, the United States may seek to enjoin the defendants from committing a specific criminal violation. The United States may also seek other injunctive relief for the benefit of the victims of the fraud. For example, the United States may seek the disgorgement of the fraud proceeds. *See Commodity Futures Trading Comm'n v. Wilshire Inv. Mgmt. Corp.*, 531 F.3d 1339, 1343-44 (11th Cir. 2008); *United States v. Durham*, 86 F.3d 70, 71 n.2 (5th Cir. 1996); *United States ex rel. Zissler v. Univ. of Minn.*, 992 F. Supp. 1097, 1108-14 (D. Minn. 1998). In a

Medicare fraud case, the bank accounts would be released to the United States for return to the Medicare Trust Fund.

IX. Fugitives

Sometimes the perpetrators of the fraud flee. If they disappear after being served with the § 1345 complaint and TRO and fail to answer the complaint, the courts will grant a motion for a default judgment. However, sometimes the perpetrators flee before they can be served.

There are certain steps that must be taken to obtain relief in cases where the defendant cannot be served. Defendants may be deemed served if the United States publishes a notice in accordance with the applicable state statute. This also provides notice of the TRO as required by Federal Rule of Civil Procedure 65(a)(1). The process of service by publication takes about 2 months.

The first step is to file a motion to extend the TRO to allow sufficient time to serve by publication. The motion should be supported by an affidavit or testimony indicating the efforts that have been made to locate individual defendants or the representatives of corporate defendants. There is authority for extending TROs beyond the two 10-day periods referenced in Federal Rule of Civil Procedure 65(b)(2). *See United States v. DBB, Inc.*, 180 F. 3d 1277, 1280 n.3 (11th Cir. 1999); *S.E.C. v. Unifund SAL*, 910 F.2d 1028, 1034 (2d Cir. 1990); *United States v. Aid Med. Equip.*, No. 05-21461-CV-MGC, D.E. 53 (S.D. Fla. Oct. 20, 2005).

The next step is to file a motion to permit service by publication. This motion must be supported by an adequate affidavit detailing sufficient diligent steps to locate the defendants. The affidavit may include evidence that the defendants are evading service or have fled. The motion should also be accompanied by the proposed "Notice of Action" that will be published. After completion of the publication, if the defendants fail to file an answer by the date set in the notice, the court will grant a motion for a default judgment.

X. Conclusion

In fast moving health care fraud schemes, the individuals controlling the fraud quickly drain the bank accounts after receiving payment and move on to the next sham company. When law enforcement is alerted in time, many § 1345 TROs result in freezing millions of Medicare dollars. The continued use of § 1345 to freeze assets is critical to recovering health care dollars that would otherwise be lost to criminals.❖

ABOUT THE AUTHOR

❑ **Ana Maria Martinez** has served as an Assistant U.S. Attorney since 1990 and is currently in the Economic Crimes Section, focusing on criminal health care fraud cases. During previous years, Ms. Martinez has worked on civil health care fraud cases as well as a variety of criminal fraud cases.✳

Health Care Fraud Sentencing: Achieving Appropriate Loss Calculations under the United States Sentencing Guidelines

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Deputy Chief
Fraud Section
Criminal Division*

*John S. Darden
Assistant Chief
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I. Introduction

After aggressively prosecuting health care fraud for over 20 years, Department of Justice (Department) statistics establish that health care fraud, as evidenced by the number of investigations and cases, continues to increase. This increase strongly suggests that fraud cannot be eradicated and the country's limited health care dollars cannot be restored merely through investigation, prosecution, imprisonment, and restitution orders. If it could, the number of those caught committing health care fraud would be decreasing. Therefore, history has taught the valuable lesson that federal prosecutors must endeavor to deter fraud in our health care system before it occurs.

Social scientists teach that deterrence can be increased by focusing on the three primary factors that impact a person's decision process. Those three factors are:

- The person's assessment of the likelihood of detection;
- The person's understanding of the severity of punishment if detected; and

- The temporal relationship between the reward of the conduct and the risk of punishment.

Thus, although the government cannot prosecute its way out of fraud, federal prosecutors can take reasoned and calculated steps to ensure that the way cases are prosecuted helps to deter crime before it occurs.

During the past 2 years, the Department has attempted to focus resources on health care fraud to increase the ability to detect fraud through the analysis of real time claims data and to bring cases to indictment within days. A portion of these efforts are discussed below in addressing the operation of the Medicare Fraud Strike Force (the Strike Force). This article addresses a key element of this effort: uniformly achieving appropriate sentences in health care fraud cases.

According to statements from cooperating health care fraud defendants, many of the people caught committing health care fraud believe that their criminal exposure is insignificant compared to the potential monetary reward. The average term of incarceration between 1995 and 2006 for those defendants who have served time for health care fraud is approximately 30 months. For some, a single day in prison is enough deterrence. However, criminals stealing large sums from the health care system are comparing the potential health care fraud sentences against other criminal endeavors. Burglary, robbery, and narcotics crimes all pose risks of longer punishment and less monetary rewards than health care fraud. Consequently, criminals are unwittingly encouraged to turn to health care fraud.

As discussed below, the community needs to understand that health care fraud is not a

victimless crime that will be punished lightly. Health care fraud should be punished commensurate with other equally damaging crimes. This article will discuss how to ensure that defendants receive appropriate and uniform sentences in health care fraud cases.

II. Increased criminal enforcement efforts

In March 2007, the Fraud Section of the Criminal Division worked with the United States Attorney's Office (USAO) for the Southern District of Florida to establish phase one of the Strike Force. The Strike Force was conceived after a detailed review of Medicare claims data from around the nation. This claims data analysis established that Miami-Dade County, Florida had the most severe concentration of health care fraud in the country. In the simplest terms, the concept behind the Strike Force was to bring traditional law enforcement techniques to health care fraud criminal activity. The premise of the Strike Force is that traditional white collar law enforcement techniques are too slow for effective deterrence in areas that have concentrations of health care fraud centered around nonexistent providers. Delay in prosecution costs the government more as targets continue to commit fraud during lengthy investigations.

Strike Force results have been dramatic. Since the inception of the Strike Force operations in 2007 federal prosecutors have indicted 187 defendants in 104 cases in both Miami and Los Angeles, the phase two site. Collectively, these defendants fraudulently billed the Medicare program for more than one-half billion dollars. The impact of the Strike Force has been felt not only in the number of prosecutions and convictions. In Miami-Dade County alone, billing by durable medical equipment (DME) companies dropped by over \$1.7 billion during the phase one operation in 2007. Thus, not only were fraudulent billings to Medicare reduced by the amounts that the Strike Force defendants would have billed but the deterrent impact was substantial. These results illustrate the success of focusing on the three key factors of effective deterrence.

One of the key components of that deterrent effect was a significant increase in the length of incarceration for convicted defendants. During phase one of the Strike Force, the average sentence of incarceration was 43 months, which is approximately 1 year longer than the average Medicare fraud sentence nationwide. Further, community awareness of substantially longer sentences achieved in phase one cases, including several in excess of 10 years, adds to the perception of punitive risk.

As with most white collar cases, the key driver of a Medicare fraud sentence under the United States Sentencing Guidelines (hereinafter Guidelines) is the amount of the "intended loss" under § 2B1.1. Federal prosecutors have not always taken consistent positions on how to calculate intended loss in Medicare fraud cases. A review of sentencing decisions in Medicare fraud cases reveals that prosecutors generally have used one of three methodologies:

- The amount billed to Medicare;
- The amount allowed under applicable Medicare fee schedules; or
- The amount actually paid by Medicare.

These various positions often appear to be based on negotiated arrangements rather than the defendant's intent. Although the facts may vary from case to case, the way to seek an appropriate sentence is to base the loss calculation on what the individual defendant intended. The best evidence of the defendant's intent in most cases is what he knowingly and willfully inserted in the false claims submitted to Medicare.

III. Defendant's individualized intent drives the appropriate loss calculation

As discussed in more detail below, the purpose of sentencing is to hold a defendant accountable for his crime. In fraud cases, that includes what the defendant intended to accomplish with his fraudulent scheme. A defendant's actions are the best evidence of his intent. In a health care fraud case, the act of filing a claim requires that a person knowingly and

willfully place an amount into the electronic or paper claim form. In most cases, this act is the best evidence of the amount the person intends to take from the Medicare program.

A. "Intended loss" includes loss that is impossible or unlikely

Under § 2B1.1, the appropriate amount of loss "is the *greater* of actual loss or intended loss." UNITED STATES SENTENCING GUIDELINES MANUAL § 2B1.1 cmt. n.3(A) (2006) (emphasis added). The Guidelines define "intended loss" as "the pecuniary harm that was intended to result from the offense . . . and . . . *includes intended pecuniary harm that would have been impossible or unlikely to occur* (e.g., as in a government sting operation, or an insurance fraud in which the claim exceeded the insured value.)" *Id.* at cmt. n.3(A)(ii) (emphasis added). As the Eleventh Circuit has stated:

It is not required that an intended loss be realistically possible. Nothing in [the notes to what is now labeled as Section 2B1.1] requires that the defendant be capable of inflicting the loss he intends. We do not agree . . . that an intended loss cannot exceed the loss that a defendant in fact could have occasioned if his fraud had been successful. These decisions are inconsistent with the concept that the calculation can be based on the intended loss.

United States v. Wai-Keung, 115 F.3d 874, 877 (11th Cir. 1997) (citations omitted); *see also United States v. Serrano*, 234 Fed. Appx. 685, 687 (9th Cir. 2007) ("We hold that the district court properly interpreted § 2B1.1 and that the court did not clearly err when it approximated the intended loss as the amounts Appellant submitted to Medicare and Medi-Cal for reimbursement."); *United States v. McLemore*, 200 Fed. Appx. 342, 344 (5th Cir. Miss. 2006) (unpublished) (allowing no setoff for the value of any Medicare or Medicaid services actually rendered or products provided and holding that the determination of the amount of loss for calculations under § 2B1.1(b)(1) requires the use of the greater of actual loss or intended loss).

In a Medicare fraud case, "actual loss" will rarely if ever exceed "intended loss." Actual loss is represented by the amount paid out by Medicare for the false claims. It is not uncommon in Medicare fraud cases for there to be numerous claims for which no money was paid out by Medicare, particularly in schemes that involve "blast billing" or instances where Centers for Medicare and Medicaid Services catch on to a scheme and deny or at least delay payment while they investigate. Thus, the question at sentencing will be what figure—the amount billed to Medicare or the amount allowed under the fee schedules—should be used to determine "intended loss."

B. Intended loss is properly based on the amount submitted minus a co-payment deduction

The mere fact that the Medicare fee schedules exist does not require that intended loss under the Guidelines be based on the amounts allowed under those schedules. The Guidelines specifically state that intended loss includes loss that would have been impossible or unlikely to occur. Thus, intended loss under the Guidelines is typically calculated by using the amount billed to Medicare minus the 20 percent co-payment deduction where it is established that a defendant understood the co-payment collection requirement, even though such amount may include loss in excess of the amount allowed under fee schedules.

In 2003 the Fourth Circuit directly addressed the issue of using the billed amount as evidence of intended loss. *United States v. Miller*, 316 F.3d 495 (4th Cir. 2003). In *Miller*, a doctor was convicted of mail fraud based on his submission of false and fraudulent claims to Medicaid, Medicare, and the West Virginia Workers' Compensation program. *Id.* at 496. At sentencing, the district court calculated intended loss as the difference between what Miller billed to Medicare (rather than what he actually received) and the amount to which he was legitimately entitled based upon the rendered services. *Id.* at 497.

Miller appealed his sentence, arguing among other things, that "the court erred in using the amount he billed to Medicare and Medicaid, rather than the payments those programs allow, in estimating the amount of loss he intended because he could not have any reasonable expectation to be paid . . . beyond what the program allows." *Id.* at 501 (internal quotation marks omitted). Miller argued, therefore, that intended loss should be limited to the allowed amount set forth in the programs' reimbursement fee schedules.

The Fourth Circuit emphatically rejected that argument, holding that "the Guidelines permit courts to use intended loss in calculating a defendant's sentence, even if this exceeds the amount of loss actually possible, or likely to occur, as a result of the defendant's conduct." *Id.* at 502. The Fourth Circuit's holding was based in part on the common sense assessment that "[a]s anyone who has received a bill well knows, the presumptive purpose of a bill is to notify the recipient of the amount to be paid." *Id.* at 504.

Other courts of appeals have approved the use of the billed amount as intended loss with much less discussion than the Fourth Circuit. *See, e.g., United States v. Mikos*, 539 F.3d 706, 714 (7th Cir. 2008) ("[The defendant] billed the Medicare program for \$1.8 million; that's the intended loss whether Medicare paid or not. . . ."); *United States v. Cruz-Natal*, 150 Fed. Appx. 961, 964 (11th Cir. 2005) (approving use of billed amount to calculate intended loss in Medicare fraud case "[b]ecause the intended loss is easily calculated and greater than the actual loss"); *Serrano*, 234 Fed. Appx. at 687.

In the *Miller* case, the court concluded that the billed amount served as prima facie evidence of the defendant's intended loss, unless the defendant offered contradictory evidence regarding his subjective intent. 316 F.3d at 504. Therefore, prosecutors may use the amount billed as the starting point for assessing a criminal defendant's intent.

C. The risks of using the allowed amount to measure intended loss

In *United States v. Singh*, 390 F.3d 168, 193-94 (2d Cir. 2004), the Second Circuit found that the defendant's testimony regarding Medicare's reimbursement rules, including the fact that Medicare paid claims based on a fee schedule and not necessarily on the amount billed on the claim form, constituted sufficient evidence to rebut an inference of intended loss. Thus, the Second Circuit held that the defendant's intended loss should be based on the "allowed amount" or the amount as calculated under the applicable Medicare fee schedules where evidence established that the defendant intended to inflict such a loss.

Although use of the allowed amount may be appropriate in certain instances, particularly in cases and schemes that exist within an otherwise legitimate enterprise, use of the allowed amount to measure loss in fraudulent enterprises risks a sentencing determination that underrepresents criminal conduct. For instance, if a defendant only intended to take an amount allowed by the computer system and the Medicare program payment formulary, why would not the defendant submit claims for that amount? If he had knowledge of the allowed amount could not he have easily claimed that amount? Medicare requires that the defendant collect the 20 percent co-payment from patients based on the amount billed to Medicare—did the defendant collect any co-payments? If so, what is the evidence of such collection and was it based on the allowed amount or the billed amount?

Further, did the defendant believe that the Medicare program never mistakenly pays above the fee schedule? Had Medicare paid the claimed amount, would the defendant have kept the money or returned the funds to Medicare saying they did not "intend" to take that much? These questions are particularly difficult to answer. After all, if a defendant really believed that Medicare was infallible, then he would never have submitted fraudulent claims because Medicare would not have paid.

By submitting fraudulent claims to Medicare, the defendant shows he knew that the program had systemic payment weaknesses that made it vulnerable to fraud. Under these circumstances, is it reasonable to believe that the defendant did not intend to keep everything that he might receive as payment from Medicare, including payments over and above the allowed amounts? Even if the defendant did not necessarily expect to receive the full amount of his bills from Medicare, he most certainly would have kept the money had it been paid. See *United States v. Geever*, 226 F.3d 186, 193 (3d Cir. 2000) (the "[defendant] may not have expected to get it all, but he could be presumed to have wanted to").

All this is not to say that, even with respect to fraudulent enterprises, the billed amount should be unconditionally applied. It is easy to think of instances in which an amount other than that billed to Medicare could constitute the intended loss. The following hypothetical situations are scenarios where the claimed or billed amount may not properly constitute the defendant's intended loss.

- A defendant submits claims information to a third-party billing company for preparation and transmission of the claims. In the course of submitting the bills to Medicare, the third-party company transposes numbers and bills Medicare for an amount higher than that reflected on the defendant's submission to the billing company.
- A defendant handwrites Claims Forms 1500 for \$500, and the Medicare processor misreads the claims as \$5000.
- A defendant has an arrangement with a third-party billing company whereby the billing company gets a percentage of the amount paid by Medicare. The defendant instructs his third-party billing company to bill Medicare \$500 per claim for each piece of DME, but to get more money the company actually bills Medicare \$700 per claim.

In each of these examples, and there are certainly numerous others, evidence could be presented that the defendant did not intend a loss in the amount

claimed or submitted to Medicare. In each of these examples, however, the focus of the inquiry is properly on the defendant's conduct and intent.

Conversely, the generalized use of the allowed amount as the intended loss based on the mere existence of a fee schedule poses a risk that a sentencing court may not properly focus on the specific intent of the defendant. This risk is multiplied when defense counsel seeks to focus attention on the victim's programmatic rules rather than the defendant's criminal intent. Case analysis reveals that defense counsel frequently focus on abstract, expert opinions about Medicare regulations and internal operating procedures. These have limited relevance to what an individual defendant intended, unless evidence is focused on the defendant's knowledge of such inner workings. Thus, unlike the billed amount, which at a minimum reflects a knowing and willful act of a defendant, the allowed amount does not, on its face, show a criminal's intent.

In addition, Medicare data from financial intermediaries often has an allowed amount of zero for unpaid claims. In this instance, is it accurate for the court, in using a sum allowed amount for all fraudulent claims, to conclude that the defendant intended to steal nothing from the Medicare program when he submitted these claims, even though they went unpaid? Of course not. So again, the question becomes, for claims in which there is no allowed amount, what did the defendant intend? The best evidence of that intent is the amount the defendant billed to the Medicare program.

D. Loss in Medicare fraud cases is not capped at "actual loss"

Finally, some misguided defense counsel have argued that intended loss in Medicare fraud cases is capped by the Guidelines based on an application note following § 2B1.1 which states as follows:

Government Benefits.— In a case involving government benefits (e.g., grants, loans, entitlement program payments), loss shall be considered to be not less than the value of the benefits obtained by unintended recipients or

diverted to unintended uses, as the case may be. For example, if the defendant was the intended recipient of food stamps having a value of \$100 but fraudulently received food stamps having a value of \$150, loss is \$50.

UNITED STATES SENTENCING GUIDELINES § 2B1.1 cmt. n. 3(F)(ii) (2006).

As a preliminary matter, this section relating to receipt of "government benefits" does not apply to Medicare fraud cases. However, some defense counsel assert that the note's language precludes use of "intended loss" in a Medicare fraud case and otherwise imposes a cap on loss. This argument is not supported by the language of the application note or by the case law.

First, the language of the application note does not impose a cap on loss. Rather, the note states that in certain cases loss "shall be considered to be *not less than*. . . ."

UNITED STATES SENTENCING GUIDELINES § 2B1.1 cmt. n.3(F)(iii) (2006) (emphasis added). Thus, to the extent that the application note applies to at all, it sets a *floor* on the amount of loss, not a *ceiling*. Further, Courts have rejected the argument that this note imposes a cap on loss. In *Miller*, the Fourth Circuit held that the amount billed to Medicare constitutes prima facie evidence of intended loss in a Medicare fraud case. In rejecting the argument regarding the application note, which at the time was contained in a different section of the Guidelines, the Fourth Circuit wrote as follows:

[N]ote 8(d) simply does not speak to the issue of whether courts can use intended rather than actual loss, but instead deals with an issue altogether different from the one to which [the defendant] would have it apply. Specifically, note 8(d) directs courts to include the diversion of government program benefits as losses, even if the government funds ultimately go to eligible recipients. In other words, in cases involving government program benefits, loss is the value of the benefits diverted, as opposed to merely the value of benefits that ultimately end up in the hands of ineligible recipients, or are used for an unauthorized purpose (emphasis omitted).

. . .

Thus, these cases make clear that note 8(d) is not meant to distinguish actual loss of government program benefits from intended loss of government program benefits, as [the defendant] would have us read it. Rather, note 8(d) clarifies that "loss" includes the amount of government program benefits diverted from intended recipients or uses, even if those funds are ultimately distributed to eligible recipients, or used for an otherwise authorized purpose.

Miller, 316 F.3d at 500-01. The Guidelines thus do not cap intended loss in Medicare fraud cases at the amount actually paid.

IV. Conclusion

In conclusion, in order to better deter health care fraud on the front end, law enforcement must:

- Do a better job of detecting health care fraud in the first instance;
- Seek consistent and appropriate punishment; and
- Move cases from identification to prosecution with greater speed.

In seeking appropriate sentences, the key question is what loss was intended by the individual defendant. In many cases, the best evidence of a defendant's intent is what he put on the claims actually submitted to the Medicare program. As discussed above, where there is evidence that a defendant has knowledge of a fee schedule or capped paid rate, then that evidence should be considered along with the claimed amount to determine what the defendant intended. This article has attempted to explain that there is not a uniformly correct method for setting the loss numbers. Rather, an individualized inquiry into the intent of the defendant should be used to determine the intended loss amount. The amount actually submitted to Medicare by the defendant is the appropriate place for this inquiry to begin.❖

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Centers for Medicare and Medicaid Services' Transition from Program Safeguard Contractors (PSCs) to Zone Program Integrity Contractors (ZPICs)

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At present, the Baltimore-based Centers for Medicare and Medicaid Services (CMS) is in the process of implementing a large-scale reorganization of its Medicare Integrity Program (MIP) contractors. This will enhance contractor effectiveness and efficiency, as well as save the government money through the streamlining of costs and consolidation of contractor activities. The reorganization will also provide tremendous benefit to the law enforcement community. They will soon be able to take advantage of a "one stop shopping" concept that will provide them with data and other information that will be more comprehensive than ever before in terms of assessing the "full picture" of potential or actual Medicare fraud, waste, and abuse scenarios.

According to the nation's newspapers, America is facing a \$60 billion dollar fraud problem with respect to Medicare, the federal health-insurance program for seniors and the disabled, and Medicaid, a joint state-federal program for the needy. *See* Carrie Johnson, *Medical Fraud a Growing Problem; Medicare Pays Most Claims Without Review*, THE WASHINGTON POST, June 13, 2008, at A1; Jay Weaver, *Medicare Assailed for Extent of Fraud*, available at http://nl.newsbank.com/nl-search/we/Archives?p_action=doc&p_docid=122CE35CEBA4; Theo Francis, *Medicare, Medicaid Managed Care Gets Scrutiny for Fraud*, WALL STREET JOURNAL (Eastern Edition), Mar. 19, 2008 at B1. According to national newspapers, total annual Medicare spending is assessed at \$429.7 billion, covering an estimated 90 million Americans. *See* Jane Zhang, *U.S. News: Medicare Ignored Its Claims Policy, Audit Says*, WALL STREET JOURNAL (Eastern Edition), Aug. 26, 2008 at A3; *see also* Theo Francis, *Medicare*,

Medicaid Managed Care Gets Scrutiny for Fraud, WALL STREET JOURNAL (Eastern Edition), Mar. 19, 2008, at B1.

With ever-rising health care costs, both federal and state governments are eager to stave off what many perceive as a Medicare program hemorrhaging from the activities of fraudsters. Beginning in the 1990s, as part of a comprehensive effort to reform health care, the Clinton Administration essentially declared war on health care fraud and abuse in America and actively recruited law enforcement to assist in its efforts. *See* MALCOLM SPARROW, LICENSE TO STEAL: HOW FRAUD BLEEDS AMERICA'S HEALTH CARE SYSTEM, 56 (Westview Press 2000). Additionally, in 1996 and 1997 Congress enacted two pieces of fraud and abuse legislation that granted a wide range of additional powers to regulators. *See id.* at 57. This legislation included the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the Balanced Budget Act of 1997 (BBA). *Id.*

Until the passage of HIPAA, Medicare contractors (fiscal intermediaries (FIs) and carriers) performed claims processing and related functions for CMS but were not obligated to perform at a specific level of effort to combat potential fraud, waste, and abuse. This made CMS particularly vulnerable to these activities. With the passage of HIPAA, however, CMS was authorized to contract with new entities, separate and apart from the FIs and carriers, whose *raison d'etre* would be identifying fraud, waste, and abuse. President Clinton referred to these new contractors as "Medicare fraud hunters" in White House press releases. *See id.* at 57-58 n.2. Using this new legislative authority, CMS (then known as the Health Care Financing Administration (HCFA)) entered into contracts with entities termed Program Safeguard Contractors (PSCs), which operated as fraud fighters. PSCs use data analysis and other activities, oftentimes in coordination with law enforcement, to fight fraud, waste, and abuse. There are currently 10 PSCs that conduct antifraud, waste, and abuse activities under Medicare Parts A and B. *See* Table 1 at p. 48. *See* Brenda Thew, PSCs to ZPICs (Aug. 4, 2008) (unpublished PowerPoint presentation)

(copy on file with author). *See* Tables 2 and 3 on pages 48 and 49 respectively, for PSC Part A and Part B jurisdictions.

In the current contracting environment, PSCs manage 15 Benefit Integrity (BI) task orders that address fraud, waste, and abuse issues associated with:

- Medicare Part A (hospital insurance; i.e., inpatient care in hospitals, inpatient stays in a skilled nursing facility, hospice care services, home health services, and inpatient care in a religious nonmedical health care institution);

See CTR. FOR MEDICARE AND MEDICAID SERV. MEDICARE & YOU 10 (2008) (CMS Publication No.10050-56 (Sept. 2007));

- Medicare Part B (medical insurance; i.e., medically-necessary services, like doctors' services, outpatient care, and other medical services that Part A does not cover, as well as some preventive services);

See CTR. FOR MEDICARE AND MEDICAID SERV. MEDICARE & YOU 14 (2008); and

- Home Health (also known as RHHI, or Regional Home Health Initiative). *Id.* Table 4 at page 49 shows the RHHI PSC jurisdiction.

The Ten PSCs

- AdvanceMed, a CSC Company
- Aspen Systems Corporation
- Cahaba Safeguard Administrators, LLC
- IntegriGuard, LLC
- Computer Sciences Corporation (CSC)
- Electronic Data Systems (EDS)
- Lifecare Management Partners
- Science Applications International, Inc. (SAIC)
- TriCenturion
- TrustSolutions, LLC

Table 1

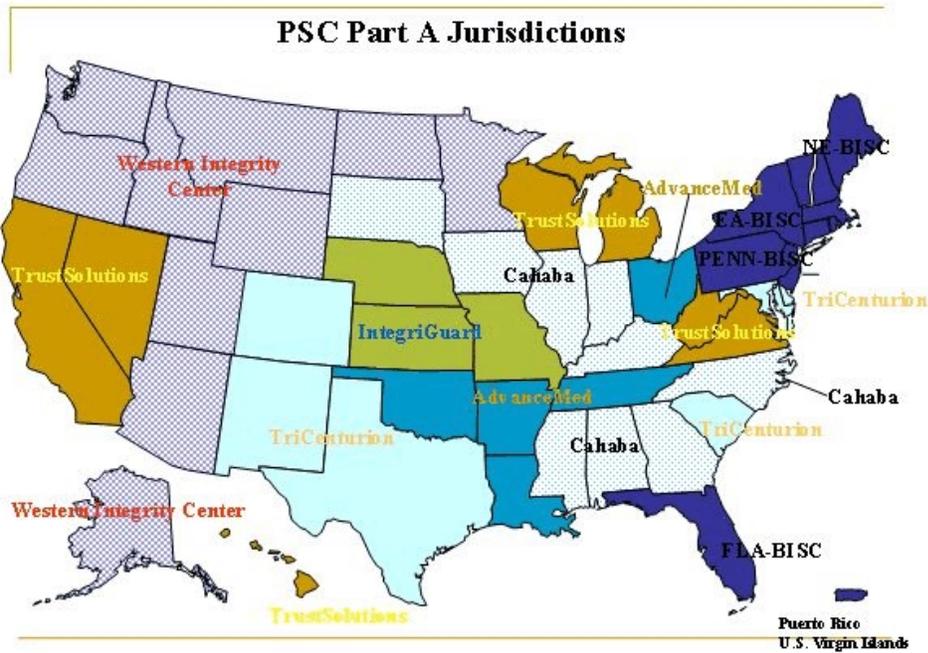


Table 2

PSC Part B Jurisdictions

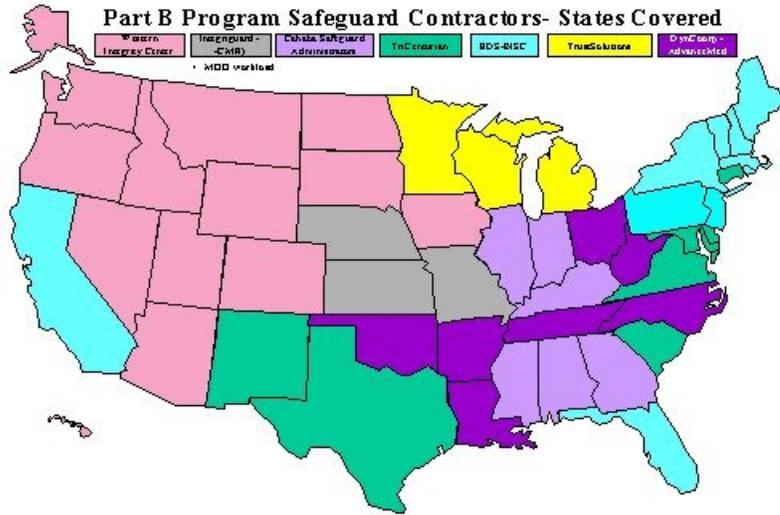


Table 3

RHHI PSC Jurisdiction



Table 4

There are also three durable medical equipment (DME) PSC task orders. *Id.*

Last but not least, some PSCs also manage the Medicare-Medicaid Data Match Program (also known as Medi-Medi). *Id.* As its name implies, Medi-Medi is a data match program whereby Medicare and Medicaid data is matched to identify improper billing and utilization patterns. *See* Lourdes Grindal Miller, *What is Medi-Medi?* (unpublished presentation) (copy on file with author). Medi-Medi began as a pilot project in California in 2001. *Id.* By September 2005, nine additional states had joined:

- Florida
- Illinois
- New Jersey
- New York
- North Carolina
- Ohio
- Pennsylvania
- Texas and
- Washington.

Id.; *see also*, Lourdes Grindal Miller, *Frequently Asked Questions about the Medi-Medi Program* (unpublished presentation) (copy on file with the author). The Deficit Reduction Act of 2005 formalized Medi-Medi and allocated ongoing funding for its expansion. *Id.* Medi-Medi is currently being expanded to a national program. *Id.*

On December 8, 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in scattered sections of 26 U.S.C. and 42 U.S.C.) (also known as the MMA), which implemented landmark reforms to the existing Medicare Program, including the organization and structure of the Medicare contractors. Specifically, § 911 of the MMA established Medicare Administrative Contractors (MACs) in place of fiscal intermediaries and carriers. *See* David Forman, *CMS Legislative Summary of H.R. 1 Medicare Prescription Drug and Modernization Act of 2003* 107 (copy on file with author). MACs collectively perform Medicare Part A and Part B work in lieu of having separate Part A and B contractors. CMS is in the process of conducting a full and open competition to transition all fee-for-service (FFS) contracts to MACs, with the goal of completing the transitions no later than the year 2011. *See* Thew at 9.

The first Medicare contractors to undergo the MAC transformation were those processing DME claims. Consequently, there are now four DME MACs, each apportioned its own jurisdiction nationally. Each DME MAC is responsible for processing DME claims for the states that lie within their respective jurisdictions. *See* Table 5 at p. 51. *See* Thew at 11. Thus, for example, the Region C DME MAC jurisdiction is responsible for processing claims in the southern portion of the country, reaching north to West Virginia, south to Florida, and west to New Mexico and Colorado.

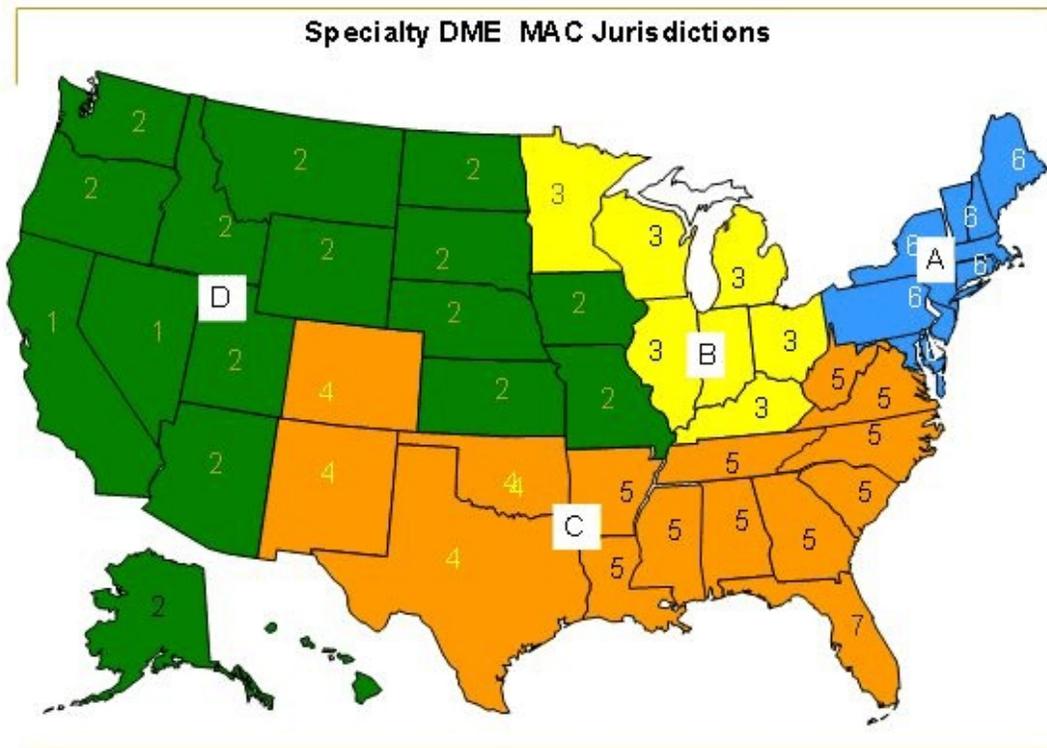


Table 5

In the interests of better cooperation and greater efficiency, CMS subsequently decided to align the DME PSC jurisdictions with the DME MAC jurisdictions so that they would be consonant with one another. CMS next determined to follow the same course with respect to the Part A and B MAC jurisdictions by aligning the PSCs with them. Under this strategy, MACs would continue to process Part A and B claims, and the PSCs would continue to perform benefit integrity work with respect to Part A and B providers.

There are 15 different Part A and B MAC jurisdictions throughout the country. *See* Table 6 at p. 52. *See* Thew at 15.

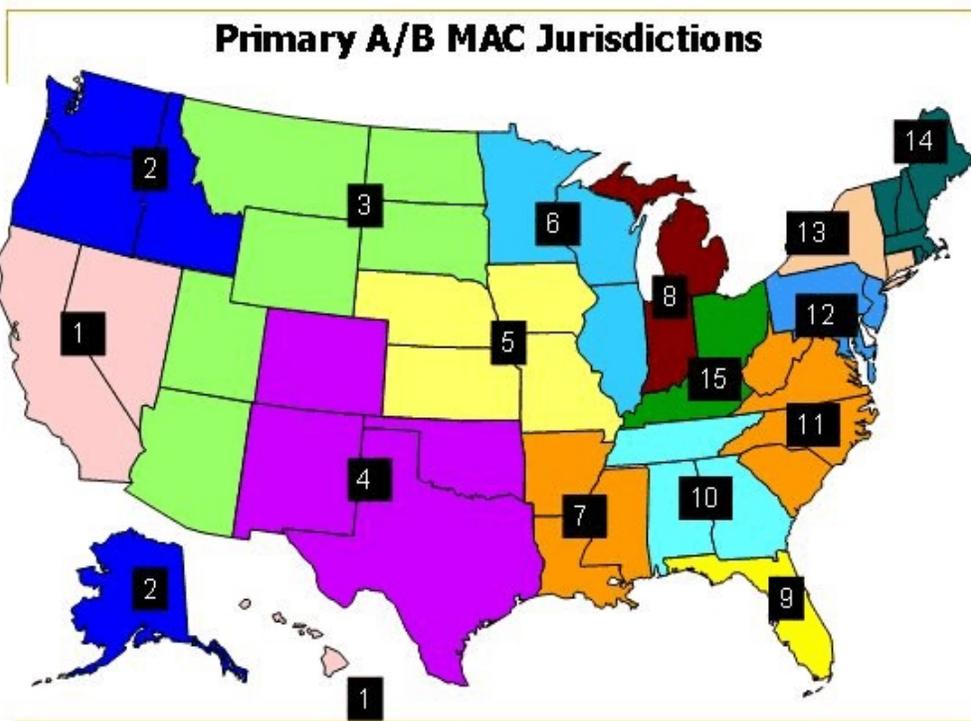


Table 6

Building on this structure, CMS decided that benefit integrity activities should be aligned with the Part A and B MAC jurisdictions. Recognizing the variation in claims volume, beneficiary populations, and potential fraud risk, CMS reconfigured the PSC task orders with MAC jurisdictions and created seven new zones for benefit integrity activities as illustrated in Table 5 *supra*. CMS is currently engaged in full and open competitions to award contracts to new entities in each zone. The new entities are called Zone Program Integrity Contractors (ZPICs) and effectively replace the PSCs. Interview with Brenda Thew, Director, Division of Benefit Integrity Management Operations, Centers for Medicare & Medicaid Services, in Baltimore, Md. (Sept. 23, 2008). As each ZPIC is awarded, the ZPIC will assume the responsibilities that, until this time, have been conducted by the PSC in the respective states in the zone. *Id.*

CMS' realignment of contractors into the seven zones reflects a recognition of the current Medicare fraud environment. Medicare fraud is more acute in certain areas of the country than in others, and therefore requires more direct attention, involvement, and resources for Medicare fraud fighters than others. For example, Zone 7 is devoted to the State of Florida, where Medicare fraud is particularly rampant. In contrast, Zone 2 will cover a vast territory of largely western and southwestern states because Medicare fraud is far less prevalent there than in places like Florida. Zones such as Florida are classified as "hot zones." Other hot zones include:

- California
- Illinois
- New York
- Texas

See Brenda Thew, PSCs to ZPICs at 17. CMS has field or regional offices in all of the hot zone states, *id.*, and ZPICs are encouraged (or in some cases, required) to maintain a physical presence in hot zones. Many times, law enforcement also has offices within close proximity of CMS offices. The coalescence of three fraud fighters, CMS, ZPICs, and law enforcement, should make for a powerful coalition in the battle against Medicare fraud in the near future.

CMS is in the process of awarding ZPIC contracts at the time of this writing. CMS has the ability to award each ZPIC a separate task order for virtually every aspect of Medicare under its contractual canopy:

- Medicare Parts A, B, DME, and Home Health;
- Medi-Medi, Medicare Part D (after 2009);
- Managed Care;

- Cost Report Audit; and
- Specialty task orders for Field Office projects.

See *id.* at 18. Each ZPIC task order will be overseen by a CMS Government Task Leader (GTL), following the current model under which GTLs monitor the PSCs.

CMS' transition to the ZPICs is expected to be a boon for law enforcement on several fronts. First, law enforcement will be able to contact one ZPIC for all of its data needs. It will provide "one-stop shopping" that will eliminate the need to visit several PSCs for data. "One-stop shopping" will save time and improve efficiency for law enforcement efforts. See Table 7 below; see Brenda Thew, PSCs to ZPICs (unpublished PowerPoint presentation) (July 25, 2008) (copy on file with author) for an illustration of the future ZPIC contracting environment.

ZPIC FUTURE ENVIRONMENT

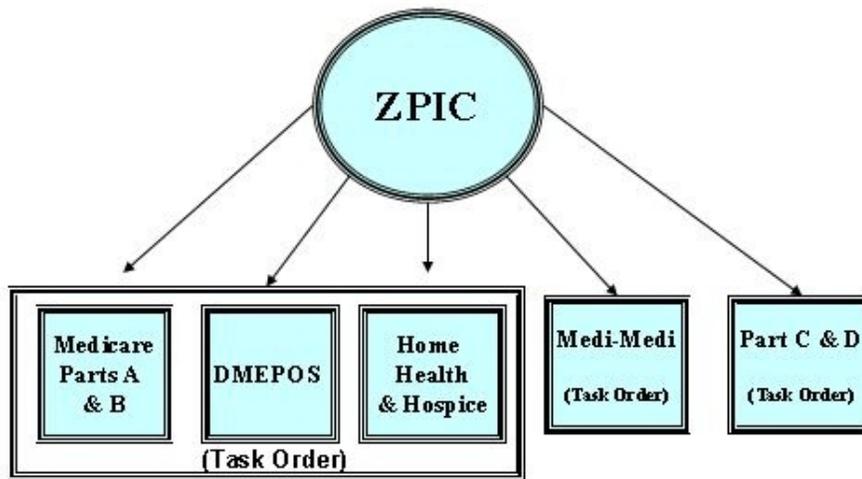


Table 7

Second, by virtue of the new ZPIC structure, where all Medicare data will be under the same roof, law enforcement will be able to obtain data across all parts of Medicare to better determine whether a provider or supplier is defrauding one or several parts of the Program. Consolidation of data, therefore, will provide law enforcement with a larger and more comprehensive picture of potential Medicare fraud a provider or supplier may be perpetrating. This consolidation will also provide more and better quality opportunities for investigating, prosecuting, and convicting fraudsters.

Third, CMS is in the process of establishing law enforcement liaisons from the law enforcement community who will assist in the coordination with ZPICs. This will enhance support to law enforcement personnel as they mount successful investigations and eventual prosecutions. Law enforcement liaisons, who are familiar with the special needs in each area of the country, will be able to coordinate closely with ZPICs to increase overall efficiency.

Similarly, CMS also expects to benefit from the new ZPIC environment. CMS expects to see an economic benefit through the consolidation of contractors and the streamlining of resources to those areas that need it most. Similarly, CMS expects state partners to save money by virtue of fewer required resources. *See* Brenda Thew, PSCs to ZPICs at 19. In sum, the new ZPIC

environment will achieve the best value for CMS by leveraging economies of scale and concentrating efforts in high fraud areas. *Id.* CMS also expects increased efficiency for the ability to look at providers across all benefit categories. *Id.* Moreover, CMS expects better coordination among contractors and their partners.

In closing, CMS' transition from PSCs to ZPICs will help law enforcement be more effective and efficient in combating Medicare fraud, waste, and abuse. CMS and its ZPIC contractors expect to provide law enforcement with the critical support needed for battling fraud, waste, and abuse in the new millennium. ❖

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"Incident to" Nothing: A Comprehensive Analysis of Physician-Billed Physical Therapy Services and Enforcement Actions Targeting Fraudulent Physical Therapy Practices

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I. Introduction

Physical therapy rendered "incident to" a physician's primary care has long been a controversial topic in the provider community. The "incident to" rule, as it is referred to, allows physicians to submit claims for reimbursement for services commonly furnished in a physician's office which are an integral, though incidental, part of the overall care provided to a patient. *See* 42 C.F.R. § 410.26(b)(2). Physicians argue that it allows for greater control over patient care because the doctor is directly involved in the physical therapy. Opponents have argued that the practice allows unskilled or uneducated individuals to render services on the physicians' behalf. While the provider community continues to debate the merits of the "incident to" rule, most will agree that the practice is susceptible to fraud and abuse. Physical therapy is one such practice area that has a demonstrated history of "incident to" abuse.

This article will address the concerns relating to physician-billed physical therapy and highlight areas that are susceptible to fraud and abuse. Further, the article will address a current joint agency enforcement initiative focusing on physical therapy billing fraud in Mississippi.

Lastly, it will discuss the positive impact recent enforcement actions and regulatory changes have had on physician "incident to" billing.

II. The troubled past

In 1994 the Office of Inspector General for the United States Department of Health and Human Services (OIG) conducted its first inquiry into the nature and extent of physical therapy provided to Medicare beneficiaries in a physician's office. *See* Office of Inspector General, "Physical Therapy in Physicians' Offices" (OEI-02-90-00590) issued March 1994, *available at* <http://www.oig.hhs.gov/oei/reports/oei-02-90-00590.pdf>. The initial study, conducted by OIG's Office of Evaluations and Inspections (OEI), revealed that nearly four out of five cases involving physical therapy provided in a physician's office did not qualify as true physical therapy services. The study found that the services: 1) were not restorative; 2) lacked complexity; 3) were not accompanied by a comprehensive plan of care; or 4) failed to include long-term goals. These shortcomings resulted in Medicare paying \$47 million in improper claims. Over the next several years, physical therapy reimbursement was studied and scrutinized by OIG. This work identified over \$1 billion in improper Medicare payments. *See generally* Office of Inspector General studies:

- "Physical and Occupational Therapy in Nursing Homes: Medical Necessity and Quality of Care" (OEI-09-97-00121) issued August 1999, *available at* <http://www.apta.org>

/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=42682;

- "Physical and Occupational Therapy in Nursing Homes: Cost of Improper Billings to Medicare" (OEI-09-97-00122) issued August 1999, *available at* <http://www.apta.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=42684>;
- "Physical, Occupational, and Speech Therapy for Medicare Nursing Home Patients: Medical Necessity, Cost, and Documentation Under the \$1,500 Caps" (OEI-09-99-00560) issued August 2001, *available at* <http://www.oig.hhs.gov/oei/reports/oei-09-99-00563.pdf>; and
- "Physical, Occupational, and Speech Therapy for Medicare Nursing Home Patients: Medical Necessity and Quality of Care Based on the Treatment Diagnosis" (OEI-09-99-00563) issued August 2001, *available at* <http://www.oig.hhs.gov/oei/reports/oei-09-99-00563.pdf>.

Providers continued to demonstrate significant noncompliance and quality of care problems, including overutilization, using unskilled staff, and billing for medically unnecessary services.

OIG initiated another study examining Medicare Part B payments for physical therapy services rendered or billed by physicians. *See* Office of Inspector General, "Physical Therapy Billed by Physicians" (OEI-09-02-00200) issued May 2006, *available at* <http://www.oig.hhs.gov/oei/reports/oei-09-02-00200.pdf>. The objective was clear: identify aberrant billing patterns and make recommendations to protect the Medicare program. *Id.* OIG undertook the task by examining physician billing patterns for physical therapy services rendered over the first 6 months of 2002. The results raised concerns about systemic abuse of the "incident to" rule relating to physician-billed physical therapy. *See id.*

From January through June 2002, Medicare paid all providers approximately \$528 million for physical therapy services billed to Part B carriers.

Id. Nearly 30 percent of these payments were made to physicians. *Id.* Based on a simple random sample, OIG determined that over 91 percent of the physician-billed physical therapy paid for by Medicare failed to meet program requirements for reimbursement. *Id.* The services failed to meet program requirements because they were not medically reasonable or necessary, not properly documented, or were unsupported by a complete plan of care. As a result, Medicare improperly paid in excess of \$136 million. *Id.* The 6-month review soon turned into a 2-year comprehensive study addressing physician-billed physical therapy services.

Physician reimbursement by Medicare for physical therapy services in 2002 totaled \$353 million. *Id.* This included a total of 15 physicians who billed in excess of \$1 million for physical therapy services. *Id.* By the end of 2004, physician reimbursement for physical therapy services jumped 44 percent, totaling \$509 million. *Id.* The number of physicians billing more than \$1 million annually jumped to 38, an increase of 250 percent. *Id.* More disconcerting was the fact that four percent of physicians who billed for physical therapy services accounted for more than half of the \$509 million paid to physicians. *Id.* This compelling data prompted the beginning of an enforcement initiative focusing on physician-billed physical therapy services.

III. Rules and regulations governing reimbursement

Physical therapy is the treatment of functional limitations to prevent or slow impairments and disabilities brought about by injury or illness. *See* Office of Inspector General, "Physical Therapy Billed by Physicians" (OEI-09-02-00200) issued May 2006, *available at* <http://www.oig.hhs.gov/oei/reports/oei-09-02-00200.pdf>. Physical therapy often includes physical manipulation of the body and can, in certain circumstances, be accompanied by machine-assisted acts performed under the supervision of a qualified individual.

The Medicare Part B program covers outpatient physical therapy services. *See* 42 C.F.R. § 410.26. Generally, physical therapy

services are performed by qualified physical therapists or physical therapy assistants in independent or stand-alone practices. *See* 42 C.F.R. § 410.60(a). A physical therapist must be licensed by the state in which he or she is practicing and have graduated from an accredited physical therapy program. *See* 42 C.F.R. § 484.4. Likewise, physical therapy assistants must be licensed, if applicable, and a graduate of an accredited 2-year program or have achieved a satisfactory grade on an approved proficiency examination. *Id.*

Medicare regulations also allow physicians to bill for physical therapy services that satisfy the "incident to" rule. *See* 42 C.F.R. § 410.26(b). Medicare Part B pays for services incident to the service of a physician if:

- The services are rendered to noninstitutional patients in a noninstitutional setting (not in a hospital).
- The services are an integral, though incidental, part of the service of a physician in the course of diagnosis or treatment of an injury or illness.
- The services are commonly furnished without charge or included in the bill of the physician.
- The services must be of a type that are commonly furnished in the office or clinic of a physician.
- The services are furnished under the direct supervision of the physician (the supervising physician, however, need not be the same physician upon whose professional service the incident to service is based).
- The service must be furnished by the physician, practitioner with an incident to benefit, or auxiliary person. 42 C.F.R. § 410.26(b)(1)-(6).

Plainly stated, the "incident to" rule allows for federal program reimbursement for services performed by physicians, or individuals under the physician's direct supervision and employ, at the full physician reimbursement rate. Early examples of "incident to" services included blood pressure measurements, x-rays, vaccination administration,

and wound care. Over time, as physicians brought more complex and specialized services into the office setting, the number of "incident to" services increased to include physical therapy.

A nonphysician provider or auxiliary person is anyone who is acting under the direct supervision of a physician, regardless of whether the individual is an employee, leased employee, or independent contractor of the physician or of the same entity that employs or contracts with the physician. *See* 42 C.F.R. § 410.26(a). Auxiliary personnel are often nurses, nurse practitioners, technicians, physician assistants, respiratory therapists, physical or occupational therapists, podiatrists, chiropractors, massage therapists, or physical therapy aides. Prior to 2005, Medicare did not require auxiliary personnel to possess any specialized education, training, or license. The regulatory changes are discussed in length in section VII.

While the "incident to" rule allows for physician reimbursement for services rendered by auxiliary personnel, it does not absolve the physician from involvement in the service. The regulations require the physician to provide direct supervision over the administration of the service. 42 C.F.R. § 410.26(a)(2). In the office setting, direct supervision means "the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure." 42 C.F.R. § 410.32(b)(3)(ii). The physician need not be in the room while the service is rendered. *Id.* If the "incident to" service is performed in a beneficiary's home, Medicare will cover it only if there is direct personal supervision. Simply put, the physician must be in the home with the auxiliary personnel if the services are billed "incident to" the physician's professional services.

Medicare has outlined three basic coverage requirements governing reimbursement for physical therapy services, regardless of the provider type or service location. First, the patient must be under the care of a physician. Second, the services must be furnished under a plan of care outlining the type, amount, frequency, and duration of the therapy. *See* 42 C.F.R.

§ 410.61(c). The plan of care must include, at minimum, the patient's significant medical history, diagnosis, physician order, therapy goals, contraindication, and the patient's understanding of the need for treatment and intended goals. *See* 42 C.F.R. § 424.24(c); *see also* Medicare Benefit Policy Manual, Publication 100-2, Chapter 15, § 220.2, *available at* <http://www.cms.hhs.gov/Manuals/downloads/bp102c15.pdf>. Third, the plan of care must be certified or recertified by the physician periodically. *See* 42 C.F.R. § 424.24(c). The physician recertification requirement is intended to ensure that the patient is responding to the treatment and allows the physician to modify or discontinue the treatment if necessary. Medicare will pay for physical therapy services rendered "incident to" a physician's professional service when the standard coverage requirements are satisfied and the physician complies with all factors set forth in 42 C.F.R. § 410.26.

IV. The Mississippi Physical Therapy Initiative

OIG examined physician-billed physical therapy services and identified several program vulnerabilities susceptible to fraud and abuse. In the wake of OIG studies, Medicare carriers and program safeguard contractors began examining physician billing patterns relating to physical therapy services. The results were consistent with OIG findings in that the data identified possible physician abuse of the "incident to" rule.

Cahaba Safeguard Administrators (CSA), the program safeguard contractor for the Medicare Part B program in Mississippi, identified a series of problematic billing trends that indicated excessive overutilization of physician-billed physical therapy services. The data analysis focused on physicians who billed specific time-based physical therapy reimbursement codes. For example, CSA identified one physician who billed the Medicare program 18.5 hours of physical therapy for one beneficiary in 1 day. In fact, CSA identified numerous examples of beneficiaries who received between 8 and 12 hours of physical therapy on a daily basis.

The data also identified several physicians who billed in excess of 150 hours of physical therapy services within a 24 hour time period. While the volume of services was staggering, the more disturbing fact was that the claims often identified the service location as the beneficiary's home. To put this into perspective, for a physician to lawfully bill 150 hours of in-home physical therapy services in 1 day, the physician would have to personally treat more than six beneficiaries an hour, all located in the same home, for 24 consecutive hours. If the in-home services were provided by auxiliary personnel under the direct supervision of a physician, the physician would be required to supervise 6 individuals, rendering treatment to 6 beneficiaries an hour, all located in the same home, 24 times a day. The data analysis raised serious doubts about the physician's ability to provide the amount of therapy that was submitted to the Medicare programs for reimbursement.

CSA referred the findings to the OIG Office of Investigations (OI). OI initiated investigations into several Mississippi physical therapy companies based on billing patterns evidencing the hallmarks of overutilization and/or the lack of physician supervision. The investigations resulted in 13 cases targeting physical therapy clinics, their respective owners and principals, and several affiliated physicians and employees suspected of fraudulently billing federal and state health care programs. The financial loss to the government was estimated to exceed \$60 million for the fraudulently rendered physical therapy services. This was the beginning of the Mississippi Physical Therapy Initiative.

As the investigations proceeded, the manner and scheme in which the clinics operated became evident. Several individuals would collectively open a clinic to provide in-home therapy services to Medicare and Medicaid beneficiaries. The owners often had little or no medical background and included an investment banker, several housewives, a nurse practitioner, a durable medical equipment (DME) supplier, a receptionist, and a drug counselor.

The clinic owners would subsequently recruit physicians to serve as medical directors. The medical directorship agreements often required little or no work on the part of the physician yet paid either an annual salary or per assessment fee. In some instances, the medical director received both types of compensation. The clinic would subsequently require the physician to reassign his or her rights to the clinic in order to receive payment under the Medicare and/or Medicaid programs. After reassignment, the clinics could bill federal and state health care programs directly using the doctor's provider number and collect payment on the doctor's behalf.

The clinics would then hire individuals with little to no medical background to serve as physical therapy "technicians." These individuals included a gas station attendant, a shoe salesman, retail cashiers, a convicted felon, a high school dropout, massage therapists, kinesiotherapists, and an exercise physiologist. The "technicians" were tasked with the responsibility of rendering unsupervised in-home physical therapy services to Medicare and Medicaid beneficiaries. No individual employed by the clinics was lawfully authorized by the State of Mississippi to render physical therapy services.

The physical therapy services were later billed under the physician's provider number as if the physician personally rendered the services or directly supervised a "technician" rendering the services. As a result, the physical therapy clinics submitted claims that were false and fraudulent in one or more of the following ways.

- First, the claims falsely purported that the physical therapy services were rendered by a physician or under the direct supervision of a physician.
- Second, the services were not medically reasonable or necessary.
- Third, the services were not rendered or did not accurately reflect the amount of services provided.
- Fourth, the services were not initiated or re-initiated by a physician's direct and personal medical evaluation every 30 days.
- Fifth, the claims falsely purported that the treatments were ordered by a physician as an integral part of his or her continuing active participation and management in the course of treatment.

In April 2007 the United States Attorney's Office for the Southern District of Mississippi (USAO) reached out to the OIG Office of Counsel to the Inspector General (OCIG) for assistance in prosecuting several of the physical therapy fraud cases. OCIG assistance was requested because the USAO did not have the resources to prosecute all of its health care fraud cases because of the unprecedented amount of Federal Emergency Management Agency (FEMA) fraud occurring in the wake of Hurricane Katrina.

The goal of the initiative was to form a collaborative partnership between OIG and the USAO to quickly and efficiently indict and prosecute the offenders. The initiative proved successful with OIG providing manpower and substantive knowledge to the formidable skill and experience of the USAO. Within 6 months, the USAO and OIG brought 7 cases before the grand jury and obtained 7 indictments against 18 individuals.

V. United States v. Canton Rehab. Serv., Inc., 3:07-CR-00096 (S.D. Miss. Aug. 22, 2007)

In January 2001 Frank Kay Wiley and Michael Anthony Yant, opened and established Canton Rehabilitation Services, Inc. (CRS) in Canton, Mississippi. Wiley and Yant opened CRS for the purpose of submitting false and fraudulent claims to the Medicare and Medicaid programs for physical therapy services. Wiley imported the scheme to defraud from Texas where he was previously an owner and operator of a rehabilitation facility. The clinic in Texas was shut down after a federal investigation revealed it had fraudulently billed for physical therapy services.

Wiley and Yant incorporated the clinic through straw persons, but controlled the day-to-day operations. The business model of CRS was distinctive in that it was the only clinic in the

investigation that rendered services in a traditional brick and mortar facility. Rather than provide in-home physical therapy services, CRS would transport beneficiaries to and from their homes for treatment via a company van. This presented a unique investigative challenge because the government needed to establish that no physician was present in the clinic during the rendering of the physical therapy services.

CRS's ability to bill federal and state programs was contingent on securing a physician's provider number. Yant, using his relationship with area physicians made through his DME company, recruited two doctors to serve as medical directors. Wiley recruited the third medical director. The medical directorship agreements required the physicians to work between 6 to 8 hours a week and paid them \$125 per patient assessment. The agreements required the physicians to consult with company administrators, supervise activities with other physicians and professionals, submit reports, admit and discharge patients, and supervise all medical care rendered by a specialist. In actuality, the physicians performed little or no work. The medical directorship agreements were a sham used to obtain the physicians' provider numbers. The physicians' only job was to sign progress notes on a weekly or biweekly basis. The physicians' per assessment fee was based on the number of patient charts reviewed by the physicians. The physicians' signature gave the appearance that they supervised the administration of the physical therapy when they had not.

Once the physicians' provider numbers were acquired, CRS sought to recruit hourly employees to serve as "technicians" who were responsible for rendering the physical therapy services to the beneficiaries. None of the employees were licensed as a physical therapist or physical therapy assistant. The employees were not trained or educated in the art or discipline of physical therapy by an authorized or accredited entity and none were authorized to render physical therapy services under the governing regulations promulgated by the State of Mississippi.

The business model was implemented to abuse the "incident to" rule. All claims for services rendered by CRS employees were submitted under one of the three medical directors' provider numbers. Each claim submitted by CRS falsely purported that the physical therapy services were rendered by a physician or under the direct supervision of a physician. At no time did any CRS physician render physical therapy services to a beneficiary. Moreover, no physician supervised a CRS employee providing physical therapy services to a beneficiary. The investigation revealed that two of the three medical directors were not present at the facility when the services were provided. One physician admitted that he never set foot in the facility. Another physician was rarely present and did not supervise any individual during the provision of the physical therapy services.

CRS submitted claims to Medicare in excess of \$3.7 million and received payments totaling over \$1.6 million. In the same time period, CRS submitted claims to Medicaid for payment in excess of \$456,362.00 and received payments totaling \$78,402.00. Wiley and Yant owned and operated a second clinic, Mississippi Central Rehabilitation (MCR), using the same manner and scheme as CRS. MCR submitted claims to federal and state health care programs totaling \$7,014,319.85 and received in excess of \$2,851,664. MCR was not charged, but the financial loss attributable to the clinic was applied at sentencing under the relevant conduct provision of the United States Sentencing Guidelines.

On August 22, 2007, Wiley and Yant were charged in a 36-count indictment alleging conspiracy, health care fraud, false claims, false statements, wire fraud, money laundering, and forfeiture. Wiley proffered and agreed to cooperate in the prosecution of Yant. Wiley entered a guilty plea to one count of making a false statement involving a health care matter in violation of 18 U.S.C. § 1035 (1996). Wiley was sentenced to 37 months in prison. In April 2008 Yant also entered a guilty plea to one count of making a false statement in a health care matter and was later sentenced to 48 months in prison.

VI. Case development: Lessons learned

The numerous OIG studies, coupled with the recent enforcement actions, highlight several concerns regarding physician "incident to" billing. See Office of Inspector General, "Prevalence and Credentials of Nonphysicians who Performed Medicare Physician Services" (OEI-09-06-00430). The investigations and analysis have allowed for the identification of particular areas susceptible to fraud and abuse and laid the framework to identify this type of program fraud. The primary challenge in developing an "incident to" case is identifying the individual who personally rendered the service. Reimbursement claim forms do not require a physician to use a modifier to identify whether the services were rendered by the physician personally or by auxiliary personnel "incident to" the physician's professional services.

Another problem related to the development of "incident to" abuse cases relates to the volume of services billed by an individual physician. Medicare does not cap the amount of services that may be billed under a particular physician's provider number. A physician is permitted to bill for an unlimited amount of services as long as the supervision requirements are met. Moreover, the regulations do not limit the number of auxiliary personnel that a physician can simultaneously supervise. Therefore, the ability to identify problematic or fraudulent billers cannot be accomplished by data analysis alone and requires additional scrutiny of the physician's business practices.

Prosecutors and investigators must take a 2-pronged approach in developing cases involving potential "incident to" abuse. First, determine whether the physician personally rendered the "incident to" service. If the physician personally rendered the service the inquiry ends. If not, the second step requires one to determine whether the physician satisfied the appropriate supervision requirement over the auxiliary personnel rendering the service.

For example, the data analysis from the Mississippi Physical Therapy Initiative demonstrated that the physicians were billing in

excess of 24 hours a day. As discussed *supra*, there were many occasions where the physician's provider number was used to bill in excess of 150 hours of physical therapy in 1 day. In this situation, the amount of time billed necessarily implied the physician was billing for services rendered by auxiliary personnel because of the impossibility that one provider can provide more than 24 hours of service in 1 day. The lawful billing of 150 hours of physical therapy services would require a physician to supervise at a minimum 6 auxiliary personnel for 24 consecutive hours. The data gave credibility to the notion that the physician was not adequately supervising the auxiliary personnel because of the high volume of services. The subsequent investigation confirmed that the physicians were part of an "incident to" scam. The answers to this relatively simple inquiry will assist prosecutors in efficiently and effectively developing successful "incident to" abuse cases.

VII. A new beginning

Recent enforcement initiatives coupled with specific regulatory changes appear to have had an impact on reducing physician abuse of the "incident to" rule involving physical therapy services. Medicare Part B billing data for the past 3 years show a sharp decline in physician "incident to" billing. In 2007 Medicare Part B paid approximately \$1.56 billion for physical therapy services. Memorandum from the Regional Inspector General for Evaluations and Inspections, Region IX to the Department of Justice (October 1, 2008) (on file with author). Physicians received \$291 million or 19 percent of the total amount of allowable physical therapy services, a decrease of approximately 43 percent from the 2004 physician-billed figure. *Id.* Over the same time period, the number of physicians that billed in excess of \$1 million for physical therapy services decreased from 38 to 6, reflecting an 84 percent reduction. *Id.* Additionally, the number of physicians that billed in excess of \$100,000 annually decreased from 992 to 279. *Id.*

The decrease is likely, in part, attributable to increased enforcement of "incident to" abuse. The

decrease may also be attributable to a 2005 regulation change addressing the qualifications of auxiliary personnel. During the Mississippi Physical Therapy Initiative, it was evident that many of the auxiliary personnel possessed little or no skill, education, or training in the field of physical therapy. Prior to 2005 Medicare expected the person providing the physical therapy to be highly knowledgeable, skilled, and trained in the field of physical therapy, but there was no expressed regulatory requirement. The regulations simply required the auxiliary personnel to:

- Be under the direct supervision of a physician; and
- Be an employee of the physician, practice group, or legal entity that employed the supervising physician.

See 42 C.F.R. § 410.26.

In 2005 the Centers for Medicare and Medicaid Services implemented a regulation mandating that auxiliary personnel possess the same education and skill level as a licensed physical therapist. See 42 C.F.R. § 410.29(c)(2). The regulation change eliminated physician "incident to" billing for services rendered by uneducated and unskilled employees. The new regulation states, "Medicare Part B pays for outpatients physical therapy services . . . if they are furnished . . . by, or incident to the service of, a physician, physician assistant, clinical nurse specialist, or nurse practitioner when those professionals may perform physical therapy services under State law." 42 C.F.R. § 410.60(a)(3)(iii). The rule further provides that when the therapy is provided "incident to" the services rendered by a physician, physician assistant, clinical nurse specialist, or nurse practitioner, the "service and the *person who furnishes the service must meet the standards and conditions that apply to physical therapy and physical therapists*, except that a license to practice physical therapy in the State is not required." *Id.* (emphasis added). In all other circumstances, Medicare mandates that the licensed physical therapist, or physical therapy assistant acting under the direct supervision of a

physical therapist, must be the professional providing the service.

VIII. Conclusion

To date the Mississippi Physical Therapy Initiative has produced seven indictments, eight guilty pleas, and approximately \$6 million in court-ordered restitution. The sentences have ranged from 4 years incarceration to 5 years probation. The convictions also resulted in program exclusions being imposed by the OIG which prohibit the convicted individual from participating in federal health care programs for a period of years. Encouraged by the early success, OIG and the USAO continue to aggressively pursue the culpable individuals and recover federal program funds.

OIG is continuing to review physical therapy bills submitted by physical therapists and physicians under Medicare's "incident to" provision. OIG hopes to create additional enforcement initiatives consistent with its overall mission to protect the federal health programs. OIG data analysts are currently identifying problematic billing patterns by applying sophisticated analytical methods to 100 percent of the Medicare claims data for targeted years. While "incident to" abuse in the practice of physical therapy has cost the federal health care programs millions of dollars in improperly paid claims, OIG believes that the continuation of aggressive enforcement initiatives similar to the Mississippi project will deter the spread and depth of "incident to" fraud.❖

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The author would like to thank Special Agents Lynn Melear, Ursula Powell, and Michael Loggins, whose hard work and dedication was vital to the success of the Mississippi Initiative. The author also thanks Don Burkhalter, Angela McRae, and the rest of the Southern District of Mississippi United States Attorney's Office for their continued support and assistance. Lastly, the author would like to thank OEI Senior Analyst Steven Zerebecki whose data analysis was instrumental in the completion of this article.